# 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): **September 19, 2023** 

# RESHAPE LIFESCIENCES INC.

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation)	1-37897 (Commission File Number)	<b>26-1828101</b> (IRS Employer Identification No.)
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18 Technology Drive, Suite 110 Irvine, CA		92618
(Address of principal executive office	es)	(Zip Code)
(Re	(949) 429-6680 egistrant's telephone number, including are	ea code)
(Formei	<b>Not applicable</b> r name or former address, if changed since	e last report.)
· ·		fy the filing obligation of the registrant under any of the
☐ Written communications pursuant to Rule 425	under the Securities Act (17 CFR 230.42	5)
☐ Soliciting material pursuant to Rule 14a-12 ur	nder the Exchange Act (17 CFR 240.14a-1	2)
☐ Pre-commencement communications pursuan	t to Rule 14d-2(b) under the Exchange Ac	t (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuan	t to Rule 13e-4(c) under the Exchange Ac	t (17 CFR 240.13e-4(c))
Securities registered pursuant to Section 12(b) of th	e Act:	
<b>Title of Class</b> Common stock, \$0.001 par value per share	Trading Symbol RSLS	Name of Exchange on which Registered The Nasdaq Capital Market
ndicate by check mark whether the registrant is an echapter) or Rule 12b-2 of the Securities Exchange Act		Rule 405 of the Securities Act of 1933 (§230.405 of this
Emerging growth company $\square$		
f an emerging growth company, indicate by check ma or revised financial accounting standards provided pure		the extended transition period for complying with any new t. $\Box$

### Item 1.01 Entry into a Material Definitive Agreement.

On September 19, 2023, ReShape Lifesciences Inc. (the "Company") entered into an Exclusive License Agreement (the "License Agreement") with Biorad Medysis Pvt. Ltd. ("Biorad"), pursuant to which the Company granted an exclusive license to Biorad to manufacture, commercialize and distribute the Company's Obalon® Gastric Balloon System in the territory of India, Pakistan, Bangladesh, Nepal, Bhutan, Sri Lanka, and the Maldives. The License Agreement provides for \$200,000 in upfront payments from Biorad to the Company and ongoing royalty payments of 4% on gross sales of the Obalon Balloon System in the territory. The License Agreement also contemplates that Biorad will become the Company's exclusive worldwide manufacturer and supplier of the Obalon Balloon System pursuant to a supply agreement to be entered into between the parties, the form of which is attached as an exhibit to the License Agreement.

The foregoing description of the License Agreement is qualified in its entirety by reference to the full text of the License Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated herein by reference.

### Item 8.01 Other Events.

On September 21, 2023, the Company issued a press release announcing the entry into the License Agreement. A copy of such press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

# Item 9.01 Financial Statements and Exhibits.

### (d) Exhibits

Exhibit No.	Description				
<u>10.1</u>	Exclusive License Agreement, dated September 19, 2023, by and between ReShape Lifesciences Inc. and Biorad Medysis				
	Pvt. Ltd.				
<u>99.1</u>	Press release dated September 21, 2023				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

# SIGNATURES

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

# RESHAPE LIFESCIENCES INC.

By: /s/ Paul F. Hickey

Paul F. Hickey
President and Chief Executive Officer

Dated: September 22, 2023

### **EXCLUSIVE LICENSE AGREEMENT**

**THIS EXCLUSIVE LICENSE AGREEMENT** (the "Agreement"), effective as of September 19, 2023 between **RESHAPE LIFESCIENCES INC.**, a Delaware corporation having a business address of 18 Technology Drive Suite 110, Irvine, California 92618 (the "**LICENSOR**"), and **BIORAD MEDYSIS, PVT. LTD 221,** a Private Limited company organized under the laws of India with Corporate office at Survey No 48/3 & 48/7, Pashan Sus Road, Taluka Mulshi, Pune, Maharasthra, India - 411021 (the "**LICENSEE**").

#### RECITALS

WHEREAS, LICENSOR owns the Licensed Technology (as hereinafter defined), for weight loss systems including a system utilizing a gastric balloon; and

WHEREAS, LICENSEE is a medical device manufacturer in India who has successfully manufactured and sold innovative medical devices in Urology, Gastroenterology, Orthopaedics and Neurovascular segments and wishes to expand into the field of bariatrics; and

WHEREAS, LICENSOR desires to license the Licensed Technology in the Licensed Field and in the Territory (as hereinafter defined), and LICENSEE desires to secure such license in order to develop, commercialize, sell, and license throughout the Territory products that embody or employ the Licensed Technology; and

WHEREAS, LICENSOR desires to establish Licensee as an exclusive world-wide supplier of Licensed Technology, to purchase the Licensed Technology as manufactured by Licensee, and commercialize and sell Licensed Technology outside of the Territory, in each case pursuant to a supply agreement to be entered into between the parties in substantially the form attached hereto as Exhibit A:

NOW THEREFORE, in consideration of the premises, and the receipt of good and valuable consideration the sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

### 1. DEFINITIONS

- 1.1 **"Accounting Period"** shall mean each three (3) month period ending March 31, June 30, September 30, and December 31 during the term of this Agreement.
- "Affiliate" with respect to each party shall mean any corporation or other legal entity controlling, controlled by, or under common control with such party. The term "control" means possession, direct or indirect, of the powers to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise.
- 1.3 **"Approval"** shall mean such approval or approvals as are necessary from an applicable Regulatory Authority for the marketing of the Products for use in the Licensed Field in a jurisdiction within the Territory.
- 1.4 "**Applicable Law**" shall mean all public laws, statutes, ordinances, codes, acts, bylaws, rules, regulations, decrees and orders of any Governmental Authority which now or hereafter may be applicable to and enforceable against the relevant work or activity in question or any part thereof.

- 1.5 **"Commercially Reasonable Efforts"** means the efforts and resources a reasonably prudent and diligent company, similarly situated as at the relevant date, would normally use to accomplish a similar objective under similar circumstances, and in addition, in the case of Licensee, not less than a level of effort made by Licensee with respect to other products or product candidates from their own research efforts or other in-licensed products at a similar stage of development or in a similar stage of product life, with similar market and commercial potential taking into account the competitiveness of the marketplace, the proprietary position of the Licensed Product, the regulatory structure involved and the profitability of the Licensed Product.
- **"Effective Date"** shall mean the date first written above.
- 1.7 **"USFDA"** shall mean the United States Food and Drug Administration and any successor thereto.
- 1.8 **"First Commercial Sale"** shall mean the first sale of any Licensed Product by LICENSEE, its Affiliates or Sublicensees, but not including transfers or dispositions of Licensed Product for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes for which LICENSEE receives no payment.
- 1.9 **"GLP"** shall mean good laboratory practice including pre-clinical toxicology studies, meeting US Good Laboratory Practice Regulations.
- 1.10 **"GMP"** shall mean good manufacturing practice of the Licensed Products, including the development of associated, devices, tools, dies, molds, and or related materials in compliance with USFDA 21 CFR Part 820 and the active version of ISO 13485.
- 1.11 "Governmental Authority" shall mean individually and collectively any governmental or regulatory authority, department, ministry, agency, court, tribunal, bureau, commission, governmental arbitrator or arbitration board or other similar body, whether federal, state or municipal.
- "Gross Sales" shall mean the Gross Sales (as defined and calculated in accordance with International Financial Reporting Standards ("IFRS")) of Licensed Products by LICENSEE or any of its Affiliates or Sublicensees ("Sellers") to a third party that is not an Affiliate or Sublicensee of LICENSEE ("Customer").

For purposes of determining Gross Sales, a "sale" shall not include transfers or dispositions for charitable, promotional purposes or for pre-clinical, clinical, regulatory or governmental testing purposes for which a Seller receives no payment.

If a Seller commercially uses or disposes of any Licensed Product by itself (as opposed to use or disposition of the Licensed Product as a component of a combination of active functional elements) other than in a bona fide sale to a bona fide Customer, the Gross Sales price of the Licensed Product for purposed of calculating Gross Sales shall be the price which would be then payable in an arm's length transaction with such a Customer. Transfer of a Licensed Product within a Seller or between or among LICENSEE and its Affiliate and Sublicensees for sale by the transferee shall not be considered a sale, commercial use or disposition for the purpose of the foregoing subsections; in the case of such transfer the Gross Sales price shall be the Gross Sales price of the Licensed Product when sold to a third party by the transferee.

1.13 **"License"** shall have the meaning ascribed to that term in Section 2.1(a).

- 1.14 "Licensed Field" shall mean the field of bariatrics.
- 1.15 **"Licensed Inventions"** shall mean the inventions claimed in the Licensed Patents.
- "Licensed Know-how" shall include all technology, materials, research data, designs, formulas, process information, manufacturing information, application information (including submissions made to US FDA from time-to-time), commercialization information, clinical data, scientific data, medical data, and any other information useful from time to time for the design, development, manufacturing, use, and/or commercialization of the Licensed Products, whether or not eligible for protection under the patent laws of the United States or elsewhere and whether or not any such technology, materials, information, data and the like related thereto, would be enforceable as a trade secret or the copying of which would be enjoined or restrained by a court as constituting unfair competition, which is developed by, or in the possession or control of, LICENSOR now or at any time during the term of this Agreement other than such information that is independently developed by LICENSEE or its agents, as evidenced by contemporaneous written records.
- 1.17 **"Licensed Patents"** shall mean any and all rights arising out of or resulting from (i) the patents and patent application set forth in Schedule 1.17 attached to this Agreement, and (ii) any letters patent granted in respect of all such applications, as well as, without limitation, any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, re-examinations, extensions, supplementary protection certificates, confirmations, registrations, revalidations and the like, of any and all such patents and patent applications and any international equivalents thereof.
- 1.18 **"Licensed Products"** shall mean the Obalon gastric balloons (all generations), and any and all related products and services, including associated weight loss systems and methods of use of such gastric balloons and related products or services provided in connection with the uses of gastric balloons alone or with various other weight loss treatments that utilize the Licensed Technology in any and all manners in the Licensed Field.
- 1.19 **"Licensed Technology"** shall mean the aggregate of the Licensed Inventions, the Licensed Know-how, and the Licensed Patents and any other information and/or technology owned or controlled by Licensor related to the Licensed Products and/or the design and/or the manufacturing of the Licensed Products.
- 1.20 "Licensed Trademarks" means the marks "ReShape®" and "Obalon®" and any additional marks that Licensor agrees in writing to allow Licensee to use in the Territory.
- 1.21 **"Patent Right"** shall mean any right, title or interest in any Licensed Patent.
- 1.22 **"Regulatory Authorities"** shall mean the governmental authorities responsible for regulating the development, marketing, and/or sales of medical device and/or pharmaceutical products in a particular country in the Territory.
- 1.23 **"Seller"** shall mean with respect to any sale of a Licensed Product the party responsible for such sale as per Section 1.10 above, where such party may be, as applicable, LICENSEE, an Affiliate of LICENSEE or a Sublicensee.

- "Sublicensee" shall mean any unrelated third party licensed by LICENSEE or by an Affiliate thereof to develop or have developed, make or have made, use or have used, sell or have sold, import or have imported any Licensed Product. For the avoidance of doubt, a wholesaler, distributor, or similar entity which purchases any Licensed Product from LICENSEE or any of its Affiliates in a bona fide arms-length transaction, shall not be deemed to be a Sublicensee. The agreement evidencing such sublicense shall contain relevant terms and conditions substantially similar to those in this Agreement and shall be subject to the review and approval by LICENSOR, such approval not to be unreasonably withheld. Notwithstanding the foregoing, if LICENSEE sublicenses to a third party who has financial wherewithal equal to or greater than the LICENSEE, the approval of LICENSEE shall not be required.
- 1.25 "Sublicense Income" means any and all payments received by LICENSEE or any Affiliate of LICENSEE in consideration of the grant of a Sublicense, including any royalties, upfront or milestone payments, equity interest, license maintenance fees and the fair-market value of any non-cash considerations.
- 1.26 **"Term"** shall mean 7 years from First Commercial Sale of each Licensed Product on product by product and country by country basis, which may be extended by the mutual written agreement of LICENSEE and LICENSOR.
- 1.27 **"Territory"** shall mean the Indian Subcontinent, which consists of the countries of Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, and Sri Lanka.

### 2. LICENSE

- 2.1 Grant of License. Subject to the provisions of this Agreement, LICENSOR hereby grants LICENSEE, including LICENSEE's Affiliates,
- (a) a royalty-bearing, Territory-wide exclusive license (the "License") in the Licensed Field to use or otherwise exploit the Licensed Technology, to develop and have developed, make and have made, use and have used, sell and have sold, offer for sale and have offered for sale, import and have imported, export and have exported, and distribute Licensed Products, and to use the Licensed Trademarks to advertise, publicize, market, and promote sales and servicing of Licensed Products by any means and in any media, including print, television, radio, outdoor, point of purchase, digital and social media, either directly or through third party distribution partners, which license shall be exclusive even as to LICENSOR, and
- (b) the right to grant bona fide sublicenses to third parties, to develop and have developed, to make and have made, use and have used, sell and have sold, import and have imported, export and have exported, Licensed Products, and to exercise all other rights under the License; *provided*, *however*, LICENSEE shall not have the right to grant any sublicense or to transfer any of its rights under the License unless each such sublicense or other transfer granted by LICENSEE contains terms and conditions under which the Sublicensee or transferee will be bound in the same manner as LICENSEE is under this Agreement, including Articles 3, 4, 6 and 7. A copy of the proposed agreement shall be provided to LICENSOR prior to the execution of the Agreement.
- 2.2 <u>Improvements.</u> All improvements to Licensed Products developed by either party during term of license shall be owned by party conceiving or developing the improvement with joint improvements owned jointly. Joint improvements to Licensed Products owned by either party may be cross-licensed on nonexclusive basis to the other party, only with the mutual written agreement of the parties, and for use in connection with the making, using selling or distributing Licensed Products in the respective territories that each party has the rights to such products. The cost for each joint improvements to be mutually agreed by LICENSOR and LICENSEE, other than the manufacturing cost which the LICENSEE will bear, taking into account the relative anticipated benefits of such joint improvement to each party.

- 2.3 **Retained Rights**. LICENSOR expressly retains all rights to the Licensed Technology not expressly licensed hereunder, including, without limitation the LICENSOR's right to practice and exploit the Licensed Technology, directly or indirectly through licensees to third parties, outside the Territory and to exclude LICENSEE from using the Licensed Technology outside the Territory.
- 2.4. Ownership and Authorized Use of the Licensed Technology and Licensed Trademarks. LICENSEE understands, acknowledges and agrees that LICENSOR is the sole and exclusive owner of the Licensed Technology and Licensed Intellectual Property, and LICENSEE shall not take any action to interfere with such ownership or authorized use. LICENSEE further understands, acknowledges, and agrees that it will not claim ownership or any other rights to the Licensed Technology or Licensed Trademarks, except as specifically granted in this Agreement. LICENSEE agrees that nothing in this Agreement shall give LICENSEE any right, title, interest or claim in or to the Licensed Technology or Licensed Trademarks, other than the right to use the same in accordance with the terms and conditions of this Agreement. LICENSEE shall execute all documents that LICENSOR may request in order to obtain or maintain a registration or to establish or to maintain LICENSOR's ownership or authorized use of the Licensed Technology or Licensed Trademarks. For avoidance of doubt, all the manufacturing and distribution licenses in the Territory shall be owned/ held by the Licensee. Licensor shall not license the Licensed Technology to any other party in the Territory.
- 2.5 <u>No Denigration</u>. LICENSEE shall not make any statement or take any action that could or might defame, denigrate, demean, disparage, ridicule or otherwise harm the goodwill and reputation of LICENSOR or the Licensed Trademarks or Licensed Technology.

### 3. DEVELOPMENT OBLIGATIONS

- 3.1 <u>LICENSEE's Obligations.</u> LICENSEE shall use Commercially Reasonable Efforts to develop and commercialize the Licensed Products at its sole expense, and, in particular, LICENSEE will be responsible for the manufacturing, preclinical, clinical, and regulatory development activities of the Licensed Products in the Territory and shall bear the full costs of such activities. LICENSEE shall specifically be responsible for the following, to the extent applicable:
  - LICENSEE To undertake all the required regulatory support/ documents for regulatory filing in the Territory for a Licensed Product.
  - · LICENSEE at its sole cost and option may conduct limited clinical trials/studies as required for the regulatory approvals. All the results and outcomes of such trials would be the property of LICENSEE.
  - the good laboratory practices ("GLP") and/or GLP pre-clinical toxicology studies, good manufacturing practices ("GMP"), meeting US Good Laboratory Practice Regulations and US FDA 21 CFR Part 820 and the active version of ISO 13485.
  - · GMP manufacturing of the Licensed Products, including the development of associated, devices, tools, dies, molds, and or related materials in compliance with USFDA 21 CFR Part 820 and the active version of ISO 13485.

In the event that LICENSEE, after using its Commercially Reasonable Efforts, decides to halt or stop development or otherwise abandons development of Licensed Products, the termination provisions of Section 9 below shall apply.

3.2 **Progress Reports.** At intervals no longer than every six (6) months, LICENSEE shall provide a written summary status report of progress made toward commercialization, summarizing achievements toward commercialization in the last six months and communicate with LICENSOR by telephone, video calls or through in-person meetings on progress made toward achieving the development and commercialization of one or more Licensed Products as acceptable to both LICENSOR and LICENSEE.

- 3.3 <u>Cooperation of LICENSOR.</u> Upon execution of the Agreement, LICENSOR, in consideration of the various continuing payment obligations of LICENSEE under Article 5 (Royalties and Milestone Payments and Equity Interest) and Article 9 (Termination), shall provide to LICENSEE reasonable assistance, and cooperation as shall be reasonably requested in writing by LICENSEE relating to the development and commercialization of Licensed Products. Such assistance shall include, without limitation providing the following information during the initial technology transfer at no additional commercial consideration:
  - · Raw material specifications and qualified vendor information
  - · Transfer MSA, if any to the extent applicable to the Territory, with vendors for raw material supply
  - · Surplus (non-expired and acceptable quality) raw material to be provided by LICENSOR, with LICENSEE responsible for all shipping, customs clearance and other costs to get such materials to India.
  - · Balloon blowing equipment to be provided by the LICENSOR. All the necessary details like qualification reports, operating manuals, troubleshooting details, maintenance requirements to be shared by the LICENSOR in a proactive manner.
  - · Complete technical files & master files to be provided
  - · Product manufacturing training, manufacturing know-how, to the extent in written form
  - · Technical and manufacturing assistance post transfer on a case-by-case basis subject to below conditions.
  - · Equipment & fixture designs, drawings & other knowhow for the manufacturing process for Licensed Products.
  - · List of key opinion leaders, if any, engaged by LICENSOR in the Territory with respect to the Licensed Products
  - · List of dealers/ distributors engaged by LICENSOR in the Territory, if any. Any existing agreements with such entities to be transferred to LICENSEE, to the extent possible or terminated when contractually and legally possible.
  - · Assistance in successful manufacturing, qualification and commercializing of the Products.

LICENSOR and LICENSEE will use their respective commercially reasonable efforts to jointly develop and agree upon a plan to provide for the transfer of knowledge to LICENSEE including all departments such as design, production, quality, regulatory, with adequate and satisfactory documentation provided, with the intent to finalize such plan within three months after the Effective Date.

3.4 <u>Provision of Product in Support of Development and Sales</u>. LICENSEE will at its sole cost manufacture or will have manufactured the finished and packaged Licensed Products in support of development activities and for commercial sales.

### 4. BRANDING, MAINTENANCE OF INTELLECTUAL PROPERTY AND QUALITY

Responsibility. LICENSOR, at its expense, shall be solely responsible, and shall have sole decision-making authority, for the preparation, filing, prosecution, enforcement and maintenance of all patent, trademark and other intellectual property rights in the Territory; provided that it is expressly agreed that LICENSOR has no obligation to file for, register, maintain, enforce or take any particular action with respect to any intellectual property right. It is completely in LICENSOR's sole discretion whether or how to protect or enforce its intellectual property rights in the Territory, and LICENSEE expressly acknowledges that LICENSEE has no right to object to any action of LICENSOR with respect to any intellectual property right. Prior to abandoning any issued patent, LICENSOR will provide LICENSEE an adequate opportunity to assume maintenance of such patent at LICENSEE's own expense before the patent goes abandoned. If LICENSEE does assume maintenance of such patent at LICENSEE's own expense, then LICENSOR, at its election, will either (a) assign such patent to LICENSEE or (b) permit LICENSEE to offset the amount of such maintenance fees against any royalties or other payments due from LICENSEE to LICENSOR under this Agreement.

With respect to intellectual property unrelated to the Licensed Products or improvements done independently by the Licensee in the Licensed Products or Licensed Technology (as referenced in section 2.2), (a) LICENSEE, at its expense, have sole decision-making authority, for the preparation, filing, prosecution, enforcement, and maintenance of all patent, trademark, and other intellectual property rights in the Territory, (b) it is completely in LICENSEE's sole discretion whether or how to protect or enforce such intellectual property rights in the Territory, and (c) LICENSOR expressly acknowledges that LICENSOR has no right to object to any action or inaction of LICENSEE with respect to any such intellectual property right.

4.2 <u>Branding of Products and Use of Licensed Trademarks.</u> All Licensed Products shall be marketed and sold under the Licensed Trademarks and LICENSEE shall not use any mark or brand with respect to the Licensed Products except those which are approved in writing by LICENSOR provided that LICENSEE can identify itself on Licensed Products as the distributor, manufacturer and or supplier as the case may be and as required by any regulatory authority to show source of goods.

With respect to products other than the Licensed Products and subject to Section 4.3(f), LICENSEE shall be allowed to launch products in their own trademarks. LICENSEE shall not be allowed to launch products that include improvements to the Licensed Products without LICENSOR's prior written consent.

### 4.3 Quality Control.

- a. Product Quality. LICENSEE agrees that Licensed Products shall be designed, manufactured, advertised, promoted, publicized, distributed and sold in a manner that is consistent with the highest safety and quality standards and in accordance with GMP, as such standards may improve during the Term.
- b. Compliance with Applicable Law. LICENSEE shall comply with all Applicable Law. LICENSEE will provide immediate notice to LICENSOR of any violations of the Applicable Law committed by or reported to LICENSEE or of which LICENSEE becomes aware or should become aware with the exercise of reasonable care.
- c. Inspections. During the Term, LICENSOR, at LICENSOR's expense, shall have the right, during normal business hours and upon 7 (seven) business days prior written notice to LICENSEE, to inspect all manufacturing facilities utilized by LICENSEE (and its contractors and suppliers to the extent LICENSEE may employ the same) in the manufacturing, packaging, warehousing and distribution of the Licensed Products as commercially reasonable, but no more than four (4) times a year as not to interfere with LICENSEE's business operations. LICENSEE shall take all necessary steps reasonably requested by LICENSOR to revise any procedures that would adversely affect the quality of the Licensed Products, and shall perform such steps within the time frame agreed upon by the Parties.

During the Terrm LICNESEE shall allow inspections by Notified Bodies/outside agencies (announced or unannounced) at the LICENSOR's expense. Access and support by LICENSEE will be provided upon the arrival of the inspector(s). LICENSEE will notify LICENSOR quality point of contact when the audit is scheduled (announced inspections). LICENSOR will also be notified when the auditor arrives as part of unannounced inspections.

- d. Samples. From time-to-time, upon LICENSOR's request, and as permitted by Applicable Law, LICENSEE shall furnish to LICENSOR, at minimal charge as required by Applicable Law, a reasonable quantity of samples and/or photographs of the Licensed Products and packaging, along with any labeling or promotional materials, if applicable, to permit LICENSOR to confirm that LICENSOR's standards are being observed.
- e. Quality Review. LICENSEE agrees to comply at all times with the quality standards and specifications that LICENSOR communicates to LICENSEE regarding the Licensed Products throughout the Term. LICENSOR can monitor the quality of the Licensed Products by inspecting production samples thereof with the intention to improve manufacturing quality of the Product.
- f. Products. LICENSEE shall manufacture, sell, distribute or promote any Licensed Products only after suitable review and written approval from LICENSOR.
- g. Approvals. All Licensor brand guidelines related to advertising and promotional materials, including but not limited to, the contents of social media posts (collectively, the "Advertising Materials") shall be followed by the Licensee.
- i. Compliance. If any changes or modifications are required to be made to any Advertising Materials in order to ensure compliance with LICENSOR's specifications or standards of quality or compliance with Applicable Law, LICENSEE agrees to make such changes with prior direction from Licensor.
- j. Co-Branding. LICENSEE agrees to follow the brand guidelines set by the LICENSOR on any Packaging, promotional, or display materials associated therewith, wherever such property owned by the LICENSOR is used. Such guidelines will not be applicable where the LICENSEE is using their own trademarks or intellectual property on the Products or Packaging.
- k. Marketing. LICENSEE shall advertise the Licensed Products or cause the Licensed Products to be advertised consistent with guidelines established by mutual agreement between LICENSOR and LICENSEE, and subject to Applicable Law.
- l. <u>Complaints</u>. LICENSEE shall collect, document and report product complaints, including third-party complaints as required by applicable laws and regulations in the territories bounded by this agreement. LICENSEE shall submit any complaints regarding the Licensed Products, including third-party complaints, on the applicable form provided by LICENSOR. LICENSEE will return to LICENSOR the product that is subject of the complaint if such product has been made available to LICENSEE and such return is reasonably feasible. LICENSOR shall share the format for reporting and also provide training to the regulatory staff for such reporting.

### 5. ROYALTIES, UPFRONT PAYMENTS

- 8.1 Royalties. During the Term applicable to each Licensed Product, LICENSEE shall pay to LICENSOR royalties in accordance with the following schedule for Licensed Products sold by LICENSEE or its Affiliates and Sublicensees. LICENSEE will pay to LICENSOR the royalty specified below, for the manufacture, use, sale, import or offer for sale of such Licensed Product in the country where such manufacture, use, sale, import or offer for sale of such Licensed Product occurs:
  - (i) four (4%) of Gross Sales of Licensed Products in any country in the Territory during the Term;
  - (ii) Twenty-five percent (25%) of all Sublicense Income received by LICENSEE, or any Affiliate of LICENSEE provided in no event shall such payments associated with sales of Licensed Products by Sublicensees be less than the foregoing royalties on Gross Sales of 4%; and
  - (iii) To the extent funds received by the LICENSEE or any Affiliate, from a Sublicensee or any other source as compensation for services or supply of materials solely in connection with developing Licensed Products for subsequent commercialization in the Territory, such funds are not considered Sublicense Income under Section 5.1(ii) and such funds shall not be subject to any royalty payment whatsoever to LICENSOR.

Only one royalty under this Section 5.1 shall be due and payable to LICENSOR by LICENSEE in respect of the sale of any Licensed Product. Royalty payments shall be made within sixty (60) days after the end of the Accounting Period in which the sale is made.

- 5.2 <u>Upfront Payments.</u> In addition to the payments provided for in Section 5.1, in consideration for access to the Licensed Technology, LICENSEE shall pay LICENSOR a one-time upfront payment of \$200,000 in two equal installments, with the first \$100,000 payment to be paid within 30 days of execution of this Agreement (the "Closing") and the second \$100,000 payment to be paid no later than the earlier of (a) three months after the First Commercial Sale of a Licensed Product by Licensee in the Territory and (b) nine months after the Closing.
- 5.3 <u>Currency.</u> All royalty payments and milestone payments under this Agreement shall be in United States Dollars. Whenever conversion from any foreign currency shall be required, such conversion shall be at the rate of exchange thereafter published in the Wall Street Journal for the business day closest to the end of the applicable Accounting Period.

#### 6. REPORTS AND PAYMENTS

- Books of Accounts. LICENSEE shall keep, and shall cause each of its Affiliates and Sublicensees, if any, to keep full and accurate books of accounts containing all particulars that may be necessary for the purpose of calculating all royalties payable to LICENSOR. Such books of account shall be kept at their principal place of business and, with necessary supporting data shall, during all reasonable times for the two (2) years next following the end of the calendar year to which each shall pertain, be open for inspection at reasonable times by LICENSOR or its designee at LICENSOR's expense for the purpose of verifying royalty statements or compliance with this Agreement. In the event that any audit performed under this Section 6.1 reveals an underpayment then LICENSEE shall make the short payment within 7 days.
- 6.2 **Quarterly Payments.** In each year the amount of royalty due and share of Sublicensee Income shall be calculated on a cash received basis on the Licensee and Affiliates and Sublicensees books as of the end of each Accounting Period as defined in Section 1.1 of this Agreement and shall be paid within the next sixty (60) day period following such date, every such payment to be supported by the accounting prescribed in Section 6.3.

- 6.3 **Accounting Reports.** With each quarterly payment, LICENSEE shall deliver to LICENSOR a full and accurate accounting to include at least the following information:
- (a) Quantity of each Licensed Product sold by LICENSEE and its Affiliate or Sublicensees (by country);
- (b) Inventory of each Licensed Product at end of each period held by LICENSEE and its Affiliate or Sublicensees (by country);
- (c) Gross Sales billed and Gross Sales received by LICENSEE or any of its Affiliates or Sublicensees ("Sellers") for the sale of each Licensed Product;
- (d) Names and addresses of all Sublicensees of LICENSEE and all revenues received from such Sublicensee; and
- (e) Total Royalties and share of Sublicense Income payable to LICENSOR.

### 7. ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

- 7.1 Infringement of Intellectual Property Rights. Each party shall promptly notify the other party of evidence of infringement in the Territory of a claim of any intellectual property rights licensed hereunder. If either party shall have supplied the other party with written evidence demonstrating prima facie such infringement of a licensed right by a third party in the Territory, LICENSEE shall have the first right, but not the obligation, to take action against such infringer on its own initiative. LICENSEE shall notify LICENSOR, within three (3) months of one party providing the other with evidence of infringement, whether LICENSEE intends to prosecute the alleged infringement. If LICENSEE notifies LICENSOR that it intends to so prosecute, LICENSEE shall (at its expense), within three (3) months of its notice to LICENSOR either (i) cause infringement to terminate or (ii) initiate and diligently prosecute legal proceedings against the infringer and in LICENSOR's name if so required by law. In the event LICENSEE notifies LICENSOR that LICENSEE does not intend to prosecute said infringement, LICENSOR may, (but is under no obligation to take any action) upon notice to LICENSEE, initiate legal proceedings against the infringer at LICENSOR's expense. No settlement, consent judgment, or other voluntary final disposition of the suit which invalidates or restricts the claims or scope of any intellectual property right may be entered into without the consent of the other party, which consent shall not be unreasonably withheld, but provided that, in the event one party ("the Objecting Party") withholds consent for a proposed settlement, the party proposing the settlement may decline to support further costs of such suit or settlement discussions, and the Objecting Party shall be required to continue such suit or settlement discussions at its own expense. LICENSEE shall indemnify LICENSOR against any order for payment that may be made against LICENSOR in such proceedings brought by LICENSEE. LICENSOR shall indemnify LICENSEE against any order for payment that may be made against LICENSEE in such proceedings brought by LICENSOR to the extent arising out of any proceedings which LICENSOR brings at its own expense pursuant to Section 7.1 following LICENSEE's decision not to prosecute any alleged infringement.
- Cooperation. In the event one party shall initiate or carry on legal proceedings to enforce any intellectual property rights against any alleged infringer, the other party shall fully cooperate with and supply all assistance reasonably requested by the party initiating or carrying on such proceedings. The party which institutes any suit to protect or enforce a Patent Right shall have sole control of that suit and shall bear the reasonable expenses (including legal fees) incurred by said other party in providing such assistance and cooperating as is requested pursuant to this Section. The party initiating or carrying on such legal proceedings shall keep the other party informed of the progress of such proceedings and said other party shall be entitled to counsel in such proceedings but at its own expense. Any award paid by third parties as the result of such proceedings (whether by way of settlement or otherwise) shall first be applied to reimbursement of the unreimbursed legal fees and expenses incurred by either party and then the remainder shall be divided between the parties as follows:

- (a) If the amount is based on lost profits, LICENSEE shall receive an amount equal to the damages the court determines LICENSEE has suffered as a result of the infringement less the amount of any royalties that would have been due LICENSOR on sales of Licensed Product lost by LICENSEE as a result of the infringement had LICENSEE made such sales, and LICENSOR shall receive an amount equal to the royalties it would have received if such sales had been made by LICENSEE, and
- (b) As to awards other than those based on lost profits, sixty percent (60%) to the party initiating such proceedings and forty percent (40%) to the other party.
- 7.3 <u>Infringement Actions by Third Parties.</u> In the event that the making, selling or using of a Licensed Product in the Licensed Field infringes the intellectual property rights of others, LICENSEE will have the first right to control any negotiation or litigation with respect thereto; however no settlement, consent judgment or other voluntary final disposition of the infringement allegation may be entered into without the written consent, which shall not be unreasonably withheld, of LICENSOR.
- 7.4 **Further Assurances; Progress Reports.** For the purpose of the proceedings referred to in this Article 7, LICENSOR and LICENSEE shall permit the use of their names and shall execute such documents and carry out such other acts as may be necessary. The party initiating or carrying on such legal proceedings shall keep the other party informed of the progress of such proceedings and said other party shall be entitled to counsel in such proceedings but at its own expense, said expenses to be offset against any damages received by the party bringing any infringement suit against a third party in accordance with Section 7.2.

### 8. INDEMNIFICATION; REPRESENTATIONS AND WARRANTIES

### 8.1 **Indemnification.**

- (a) Either Party shall indemnify, defend and hold harmless other party and its directors, officers, employees, independent contractors, and agents and their respective successors, heirs and assigns (each an "Indemnitee" under this Section 8.1(a)), against any liability, damage, loss or expense (including reasonable attorney's fees and expenses of litigation) (collectively, "Losses") incurred by or imposed upon such Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments arising out of any theory of product liability (including, but not limited to, actions in the form of tort, warranty, or strict liability) concerning any Licensed Product made, used or sold pursuant to any right or license granted under this Agreement to the extent such Losses are attributable to such Party's negligence or breach of this Agreement, other than Losses arising out of claims of infringement of intellectual property rights held by third parties by the practice of the Licensed Inventions, the existence of which rights constitute a breach of the representations and warranties given by other party under Section 8.2(b) or (c).
- (b) Either Party shall indemnify, defend and hold harmless other party and its directors, officers, medical and professional staff, employees, independent contractors, and agents and their respective successors, heirs and assigns (each an "Indemnitee" under this Section 8.1(b)), against Losses incurred by or imposed upon such Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments(including, but not limited to, actions in the form of tort, warranty, or strict liability) arising out of any claims of infringement of intellectual property rights held by third parties by the practice of the Licensed Inventions, the existence of which rights constitute a breach of the representations and warranties given by other party under Section 8.2(b) or (c); provided that in no event shall either party's liability for this indemnity and defense obligation exceed in the aggregate the total amount of Consideration actually paid to other under this Agreement.

- (c) No Indemnitee under clause (a) or clause (b) of this Section 8.1 shall be entitled to any indemnification under such clause for any Loss to the extent that such Loss is attributable to the negligent activities, reckless misconduct or intentional misconduct of such Indemnitee.
- (d) Any Indemnitee under clause (a) or clause (b) of this Section 8.1 shall give the party from whom indemnification under such clause is sought (the "Indemnitor") prompt written notice of any Losses or discovery of fact upon which such Indemnitee intends to base a request for indemnification under such clause, *provided*, *however*, that an Indemnitor's obligations to such Indemnitee under this Section 8.1 shall not be rendered inapplicable as a result of the failure by such Indemnitee to notify such Indemnitor as required under this Section 8.1(d), unless such failure materially prejudices such Indemnitor's ability to take action with respect to any such Loss.
- (e) Each Indemnitor under this Section 8.1 agrees, at its own expense, to provide attorneys reasonably acceptable to an Indemnitee under this Section 8.1 to defend against any actions brought or filed against such Indemnitee with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought. Each Indemnitee under this Section 8.1 shall be entitled to participate in, but not control, the defense of such action and to employ counsel of its own choice for such purpose; *provided*, *however*, that such employment shall be at such Indemnitee's own expense.
- (f) Each Indemnitor shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of any Loss, on such terms as such Indemnitor, in its sole discretion, shall deem appropriate.

### 8.2 **Representations and Warranties.**

Mutual representations:

(a) LICENSOR and LICENSEE represent and warrant to each other that: (i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (ii) it is duly authorized and has Board approval, in the case of LICENSEE and manager/member approval in the case of LICENSOR, to execute and delivery this Agreement and to perform its obligations hereunder and thereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate/company action; (iii) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulations of any court, governmental body or administrative or other agency having jurisdiction over it; (iv) neither it nor any of its Affiliates have been debarred or is subject to debarment and will not use in any capacity, in connection with the services to be performed under this Agreement, and person who has been debarred pursuant to Section 306 of the United States Food, Drug and Cosmetic Act or who is subject of conviction in such section.

### LICENSOR represents to LICENSEE that:

- (a) To the best of LICENSOR's actual knowledge with respect solely to its Licensed Technology, as of the Effective Date there is no fact or circumstance that would prevent the use of the Licensed Technology to develop Licensed Products that could be Approved by a Regulatory Authority.
- (b) LICENSOR is the sole and exclusive owner of all right, title and interest in and to the Licensed Patents originally listed on Schedule 1.13 and such rights, and all other rights granted to LICENSEE under the License existing as of the date hereof, are not subject to any encumbrance, lien or claim of ownership by any third party. LICENSOR has obtained all necessary assignments and made all appropriate filings with respect thereto in order to secure its sole and exclusive ownership rights in and to such patent rights, and all other rights granted to LICENSEE as of the date hereof. During the term of this Agreement, LICENSOR shall not knowingly take any action that would encumber the rights granted to LICENSEE hereunder.
- (c) Except for the grant by LICENSOR to LICENSEE of the License and other rights in Article 2, which relate solely to the Licensed Product, LICENSOR has not, directly or indirectly, expressly or by implication, by action or omission or otherwise (i) assigned, transferred or conveyed any right, title or interest in or to the Licensed Technology in the Territory and/or any other rights granted to LICENSEE in the Territory under the License, (ii) granted any license or other right, title or interest in or to the Licensed Technology in the Territory and/or any other rights granted to LICENSEE under the License.
- (d) LICENSOR acknowledges that, there is no actual or threatened infringement by a third party of the Licensed Technology in the Territory.
- 8.3 <u>Limitation on Damages and Disclaimer.</u> WITH THE EXCEPTION FOR INTENTIONAL MISCONDUCT OR GROSS NEGLIGENCE OF SUCH PARTY, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, COLLATERAL, EXEMPLARY, PUNITIVE, OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF INCOME, PROFIT OR SAVINGS, OF ANY PARTY, INCLUDING THIRD PARTIES, REGARDLESS OF THE FORM OF THE ACTION OR THE THEORY OF RECOVERY, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

OTHER THAN WARRANTIES SET FORTH HEREIN, EACH PARTY MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADEMARK, SOFTWARE, TRADE SECRET, TANGIBLE RESEARCH PROPERTY, INFORMATION OR DATA LICENSED OR OTHERWISE PROVIDED TO THE OTHER PARTY HEREUNDER AND HEREBY DISCLAIMS THE SAME.

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO OTHER PARTY HEREUNDER UNDER ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION, BREACH OF THIS AGREEMENT FOR AN AMOUNT IN EXCESS OF THE ACTUAL AMOUNTS PAID HEREUNDER TO LICENSOR BY LICENSEE. EITHER PARTY MAXIMUM LIABILITY TO LICENSEE HEREUNDER IN THE AGGREGATE WILL NOT EXCEED THE AMOUNTS PAID TO LICENSOR HEREUNDER.

8.4 <u>Insurance</u>. Licensee will maintain insurance in amounts and areas of coverage that are considered commercially reasonable in this industry. The Licensee will obtain such insurance coverages and will provide each other with proof of such insurance coverage.

#### 9. TERMINATION

- 9.1 <u>Upon Expiration of Term.</u> Unless otherwise terminated as provided for in this Agreement, upon expiration of the Term of any Licensed Product on a country-by-country basis the License, with respect to such country and such Licensed Product, will be automatically converted to a fully paid-up, royalty–free, non-exclusive perpetual license that grants LICENSEE the same bundle of rights as the License, including all the rights under Section 2.1(b) to grant sublicenses.
- 9.2 <u>Upon Default.</u> If either party shall fail to faithfully perform any of its obligations under this Agreement, the non-defaulting party may give written notice of the default to the defaulting party. Unless such default is corrected within sixty (60) days after such notice, the notifying party may terminate this Agreement upon thirty (30) days prior written notice; *provided*, *however*, in the event that prior to the expiration of any such sixty (60) day period, such breaching party has in good faith commenced to use commercially reasonable efforts to remedy such breach and the completion of such remedy, due to reasons beyond the control of such breaching party, requires more than sixty (60) days to complete, then such sixty (60) day period shall be extended for so long as such breaching party is continuing in good faith to use commercially reasonable efforts to remedy such breach.

LICENSOR fails to transfer the licensed Know-how under this agreement within the period of 6 months from the date of this agreement then LICENSEE shall have right to termintate this agreement by giving 15 (fifteen) days prior notice to LICENSOR. In such case, the liability of the LICENSOR shall be the actual damages of the LICENSEE.

- 9.3 <u>If Commercially Unfeasible.</u> LICENSEE may terminate this Agreement on thirty (30) days written notice to LICENSOR, without penalty and at any time, if LICENSEE, at its sole discretion, determines that further development, manufacture, and/or sales of the Licensed Products will be commercially unfeasible.
- 9.4 **Effect on Sublicenses.** In the event that the License granted to LICENSEE under this Agreement is terminated, any sublicense under such License granted prior to termination of said License shall remain in full force and effect, provided that:
- (a) the Sublicensee is not then in breach of its sublicense agreement;
- (b) the Sublicensee agrees to be bound to LICENSOR as the licensor under the terms and conditions of this Agreement, as modified by the provisions of this Section 9.4;
- (c) LICENSOR shall have the right to receive any payments payable to LICENSEE under such sublicense agreement to the extent that they are reasonably and equitably attributable to such Sublicensee's right under such sublicense to use and exploit Patent Rights in the Licensed Patents and other rights granted in the License;
- (d) the Sublicensee agrees to be bound by the development and commercialization obligations of LICENSEE pursuant to Article 3 (whether set by the parties or by arbitration) in the field and territory of the sublicense;
- (e) LICENSOR has the right to terminate such sublicense upon thirty (30) days prior written notice to LICENSEE and such Sublicensee in the event of any material breach of the obligation to make the payments described in clause (c) of this Section 9.3, unless such breach is cured prior to the expiration of such thirty (30) day period, and shall further have the right to terminate such sublicense in the event of Sublicensee's failure to meet its development obligations pursuant to clause (d) hereof; and

- (f) LICENSOR shall not assume, and shall not be responsible to each Sublicensee for, any representations, warranties or obligations of LICENSEE to such Sublicensee, other than to permit such Sublicensee to exercise any rights to the Patent Rights in the Licensed Patents and other rights under the License that are granted under such sublicense agreement consistent with the terms of this Agreement.
- 9.5 **Payments.** Upon termination of the License granted hereunder, either Party shall pay the Other Party all royalties, milestone payments, Upfront Payments and any other amounts due or accrued up to and including the date of termination and (ii) for twelve (12) months following the date of termination, the sale of Licensed Products manufactured prior to the termination date, if LICENSEE and LICENSOR separately agree to conduct such sales.

### 10. CONFIDENTIAL INFORMATION

- 10.1 **Definitions.** Each party receiving information (the "Receiving Party") disclosed to it by the other party (the "Disclosing Party") acknowledges that by reason of its relationship to the Disclosing Party hereunder, between the parties, will have, or has had, access to certain information and materials, including the terms of this Agreement and information concerning the Disclosing Party's business, plans, technology, products and/or services that are confidential and of substantial value to the Disclosing Party ("Confidential Information").
- Obligation to Protect Confidential Information. Each Receiving Party agrees that it shall (i) take every reasonable precaution to protect the confidentiality of Disclosing Party's Confidential Information from unauthorized access or use and (ii) not use the Disclosing Party's Confidential Information in any way for the Receiving Party's own account or the account of any third party except for the purposes of performing its obligations under this Agreement. Upon termination of this Agreement and at the request of the Disclosing Party, the Receiving Party will return to Disclosing Party all of the Disclosing Party's Confidential Information in its possession or within its control or destroy such Confidential Information and certify in writing to the Disclosing Party that all such information has been destroyed; however, Receiving Party shall have the right to retain one (1) copy of the Disclosing Party's Confidential Information solely for the purpose of determining Receiving Party's obligations under this Agreement.
- Exclusions. Confidential Information does not include any information that the Receiving Party can demonstrate by written records: (a) was known to the Receiving Party prior to its disclosure by the Disclosing Party; (b) was independently developed by the Receiving Party without use of or reference to the Disclosing Party's Confidential Information; (c) was or becomes publicly known through no wrongful act of the Receiving Party; (d) was rightfully received from a third party whom the Receiving Party had reasonable grounds to believe was authorized to make such disclosure without restriction; or (e) has been approved for public release by the Disclosing Party's prior written authorization. Further, if the Receiving Party is required to disclose Confidential Information pursuant to a subpoena, court order or other similar process ("Court Order"), it is agreed that the Receiving Party shall provide the Disclosing Party with notice of such request(s), to the extent that such notice is legally permissible, so that the Disclosing Party may seek an appropriate protective order. In the event that the Disclosing Party is not successful in obtaining a protective order and the Receiving Party is compelled to disclose the Confidential Information, the Receiving Party may disclose such information solely in accordance with and for the limited purpose of compliance with the Court Order without liability hereunder.

- Disclosures Required by Law. In addition, either party may disclose, on a confidential basis, the existence and terms of this Agreement to existing or potential investors in such party, or in connection with a private or public offering of such party's securities. Furthermore, either party may disclose, on a confidential and need-to-know basis, the existence and terms of this Agreement and the proposed terms of this Agreement to its counsel, accountants, directors and other similar advisors (the "Representatives"). The foregoing shall not, however, operate or grant either party any rights under any patents, trade secrets, copyrights, or any other proprietary rights of the other party.
- 10.5 **Remedies.** The parties acknowledge that money damages would be both incalculable and an insufficient remedy for any breach of the confidentiality provisions of this Agreement, and that any such breach would cause the other party irreparable harm. Accordingly, the parties hereto agree that in the event of any such breach or threatened breach hereof by a party or by its respective Representatives, the other party to this Agreement shall be entitled, in addition to any other available remedies at law, to seek equitable relief, including injunctive relief and specific performance without the posting of any bond or other security.

### 11. MISCELLANEOUS

- 11.1 Entire Agreement. This Agreement constitutes the entire understanding between the parties with respect to the subject matter hereof.
- 11.2 **Notices.** All notices and other communications required or permitted under this Agreement shall be in writing and shall be sent by registered or certified mail (return receipt requested and postage prepaid), or delivered by hand, by messenger or by a recognized overnight delivery service or Email, addressed to each party as follows:

### if to LICENSOR:

ReShape Lifesciences Inc. 18 Technology Drive Suite 110 Irvine, California 926183 Attn: Paul Hickey, Chief Executive Officer Email: phickey@reshapelifesci.com

### With a copy to:

Fox Rothschild LLP 33 South Sixth Street, Suite 3600 Minneapolis, MN 55402 Attn: Brett Hanson

Email: bhanson@foxrothschild.com

### if to LICENSEE:

Mr. Hemant Joshi Biorad Medisys Private Limited Survey No. 48/3 & 48/7, Pashan Sus Road, Sus Village, Taluka Mulshi, Pune Maharashtra 411021, India Email: Hemant.joshi@bioradmedisys.com

### With a copy to:

Jitendra M Hegde Biorad Medisys Private Limited Survey No. 48/3 & 48/7, Pashan Sus Road, Sus Village, Taluka Mulshi, Pune Maharashtra 411021, India Emaill: jmhegde@bioradmedisys.com

Each such notice or other communication shall for all purposes of this Agreement be treated as effective or having been given (i) if sent by registered or certified mail, the earlier of receipt and five (5) business days after dispatch, and (ii) if delivered in person, by messenger, or by overnight courier, on the business day delivered.

- 11.3 <u>Amendments; Waivers.</u> This Agreement may be amended or any of its terms or conditions may be waived only by a written instrument executed by the parties or, in the case of a waiver, by the party waiving compliance. The failure of either party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either party of any condition shall be deemed as a further or continuing waiver of such condition or term or of any other condition or term.
- Assignment, Successors. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors and permitted assigns; provided that this Agreement shall not be assignable by LICENSOR without LICENSEE's written consent (which consent shall not be unreasonably withheld, delayed or conditioned) except for the right to receive royalties or other payments payable herein, and further provided that LICENSEE may, with the consent of LICENSOR (which consent shall not be unreasonably withheld, delayed or conditioned), transfer its interest or any part thereof under this Agreement to a wholly-owned subsidiary of LICENSEE or to any assignee or purchaser of the portion of its business associated with the manufacture and sale of Licensed Product, so long as such transferee assumes and agrees to be bound by the provisions of this Agreement.
- 11.5 **Force Majeure.** Any delays in or failures of performance by either party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the party affected, including but not limited to: acts of God, pandemic, acts, regulations, or laws of any government, strikes or the concerted acts of workers, fires, floods, explosions, riots, wars, rebellion, and sabotage. Any time for performance hereunder shall be extended by the actual time of delay caused by such occurrence; *provided*, *however*, that either party shall have the right to terminate this Agreement if any such extension endures for more than six (6) consecutive months.
- 11.6 **Publicity.** Neither party shall use the name of the other party or any staff member, officer, employee or student of the other party or any adaptation thereof in any advertising, promotional or sales literature, publicity or in any document employed to obtain funds or financing without the prior written approval of the party or individual whose name is to be used. Notwithstanding the foregoing, the parties agree that LICENSOR may disclose this Agreement as may be required under U.S. federal law or regulation (including any reporting requirements of the U.S. Securities and Exchange Commission or the Nasdaq Stock Market) applicable to LICENSOR as a publicy-traded company.
- 11.7 **Governing Law.** This Agreement shall be governed by and construed and interpreted in accordance with the laws of the India and Pune Court shall have exclusive jurisdiction for all operational and other matters related to execution, commercialization of the Agreement. For matters related Intellectual Property Rights shall have jurisdiction of State of Delaware, without regard to its choice of law principles.

- Alternative Dispute Resolution. For any and all claims, disputes, or controversies arising under, out of, or in connection with this Agreement, then either party may after such sixty (60) day period advise the other party of its intent to pursue such claim, dispute, or controversy in Alternative Dispute Resolution (ADR) in a writing which describes in reasonable detail the nature of such dispute. By not later than five (5) business days after the recipient has received such notice of dispute, each party shall have selected for itself a representative who shall have the authority to bind such party and shall additionally have advised the other party in writing of the name and title of such representative. By not later than ten (10) business days after the date of such notice of dispute, such representatives shall agree upon a third party, which is in the business of providing Alternative Dispute Resolution (ADR) services (hereinafter, "ADR Provider") and shall schedule a date with such ADR Provider to engage in ADR. Thereafter, the representatives of the parties shall engage in good faith in an ADR process under the auspices of the selected ADR Provider. If within the aforesaid ten (10) business days after the date of the notice of dispute the representatives of the parties have not been able to agree upon an ADR Provider and schedule a date to engage in ADR, or if they have not been able to resolve the dispute within thirty (30) business days after the conclusion of ADR, the parties shall have the right to pursue any other remedies legally available to resolve such dispute in either the state or federal courts of India for all the operational matters and of the State of Delaware for all the disputes related to Licensed Know-How and Intellectual Property rights, to whose jurisdiction for such purposes each of LICENSOR and LICENSEE hereby irrevocably consents and submits. Notwithstanding the foregoing, nothing in this Section 11.8 shall be construed to waive any rights or timely performance of any obligations exi
- 11.9 <u>Severability.</u> If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable law from time to time in effect during the term thereof, it is the intention of the parties that the remainder of this Agreement shall not be affected thereby. It is further the intention of the parties that in lieu of each such provision which is invalid, illegal or unenforceable, there be substituted or added as part of this Agreement a provision which shall be as similar as possible in economic and business objectives as intended by the parties to such invalid, illegal or enforceable provision, but shall be valid, legal and enforceable.
- Independent Contractors. It is expressly agreed that LICENSOR, on the one hand, and LICENSEE, on the other hand, shall be independent contractors and that the relationship between the two parties shall not constitute a partnership, joint venture or agency. Neither LICENSOR, on the one hand, nor LICENSEE, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other party to do so. All persons employed by a party shall be employees of such party and not of the other party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such party.
- 11.11 <u>Survival.</u> Sections 5, 6, 8, 9 10 and 11 shall survive the expiration or termination of this Agreement.
- 11.12 <u>Counterparts.</u> This Agreement may be executed in two counterparts, each of which shall be enforceable against the party actually executing such counterpart, and both of which together shall constitute one instrument.
- 11.13 **<u>Titles and Subtitles.</u>** The titles and subtitles used in this Agreement are used for convenience only and are not considered in construing or interpreting this Agreement.

[signature page follows]

THE PARTIES have duly executed this Exclusive License Agreement as of the date first shown above written.

LICENSOR: LICENSEE:

RESHAPE LIFESCIENCES INC.

BIORAD MEDYSIS, PVT. LTD

By: /s/ Paul Hickey By: /s/ Jitendra M Hegde

Name:Paul HickeyName:Jitendra M HegdeTitle:Chief Executive OfficerTitle:Managing Director

# Schedule 1.17

# <u>List of Patent Applications</u>

Application Number	Expiry Date	Live or dead status	Application Date	Publication Date	
202017007138	09-Jul-2038	Live	19-Feb-2020	28-Aug-2020	
201717038008	25-May-2036	Live	26-Oct-2017	05-Jan-2018	

# Exhibit A

# Form of Supply Agreement

# SUPPLY AGREEMENT

<b>This Supply Agreement</b> (this " <u>Agreement</u> ") is entered into as of, 2023 (the " <u>Effective Date</u> "), by and between Biorad Medysis, PVT. LTD, a private limited company organized under the laws of India (" <u>Biorad</u> "), and ReShape Lifesciences Inc., a Delaware corporation " <u>ReShape</u> "). ReShape and Biorad are referred to in this Agreement collectively as the " <u>Parties</u> ," and individually as a " <u>Party</u> ."
Whereas, Biorad and ReShape are parties to that certain Exclusive License Agreement, dated, 2023 (the " <u>License Agreement</u> "); and
<b>W</b> HEREAS, as contemplated by the License Agreement, ReShape desires to purchase from Biorad, and Biorad desires to manufacture and supply to ReShape, the Product as ReShape may order from time to time pursuant to the terms and conditions as set forth herein.
<b>Now, Therefore</b> , in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which is nereby acknowledged, the Parties pagree as follows:
ARTICLE 1
<u>DEFINITIONS</u>
1.1 <u>Reference to License Agreement</u> . All capitalized terms used but not otherwise defined in this Agreement have the meanings assigned to hem in the License Agreement. In addition to the other terms defined elsewhere in this Agreement, for the purposes of this Agreement, the following terms shall have the meaning set forth below:
"Biorad Facility" means the facility located at to be used to manufacture the Product.
"Confidential Information" means all information disclosed or provided by a Party to the other Party pursuant to this Agreement, including, narketing, financial, personnel and other information, inventions, know-how or data, in each case whether in oral, written, graphic or electronic form.
"Current Good Manufacturing Practice" or "cGMP" means the then-current standards for Good Manufacturing Practices, as defined in FDA rules and regulations or as defined in another Regulatory Authority's rules and regulations, that apply to the manufacture of Product, including, without imitation, (a) the United States regulations set forth in Title 21 of the United States Code of Federal Regulations Parts 11, and 820 and the corresponding regulation of any other applicable Regulatory Authority;(b) the International Organization for Standardization (ISO) 13485 and (c) all additional Regulatory Authority documents that correspond to, replace, amend, modify, supplant or complement any of the foregoing.
"FD&C Act" means the United States Food, Drug and Cosmetic Act, as amended, and any regulations promulgated thereunder.
" <u>Latent Defect</u> " means, with respect to any non-conformance with cGMP or the Product Specifications, that such non-conformance hereof is not visible or easily detectable without any analysis in a laboratory.
"Non-Conforming Product" means a Product that has not been manufactured in accordance with cGMP, or the Product Specifications, including containing any Obvious Defect or Latent Defect.
1.

"Obvious Defect" means, with respect to any non-conformance with cGMP or the Product Specifications, that such non-conformance is visible or easily detectable without any analysis in a laboratory.

"Product" means ReShape's Obalon® balloon system and related items described on  $Exhibit\ A$  (as it may be amended from time to time by mutual written agreement of the Parties).

"<u>Product Specifications</u>" means those specifications, characteristics, formulae, labeling, and packaging requirements and standards for such Product as set forth in <u>Exhibit B</u>, as the same may be amended or supplemented from time to time by mutual written agreement of the Parties.

"Regulatory Approval" means, for a particular country, approval by the applicable Regulatory Authority of any and all filings required for the commercial marketing or sales of a medical device in such country, along with satisfaction of any related applicable regulatory requirements.

"Regulatory Authority" means the FDA in the United States or the equivalent regulatory authority or entity having the responsibility, jurisdiction, and authority to approve the manufacture, use, importation, packaging, labeling, marketing and sale of medical devices in any country other than the United States.

### **ARTICLE 2**

### **SUPPLY OBLIGATIONS**

- 2.1 **Manufacture and Supply**. Biorad agrees to manufacture and supply to ReShape, and in accordance with the terms of this Agreement, the Product in quantities to be set forth on Purchase Orders submitted to Biorad from time to time by ReShape under Section 2.3.
- 2.2 **Forecasting.** Upon execution of this Agreement, ReShape shall deliver to Biorad a written twelve (12)-month rolling forecast for deliveries of Product to ReShape ("Forecast"). Each Forecast shall be a good faith estimate of quantities of Product that ReShape plans to order from Biorad and shall not be binding on either Party. Biorad shall use commercially reasonable efforts to meet fluctuations in ReShape's demand for Product, and shall notify ReShape as promptly as practicable if at any time Biorad has reason to believe that it will not be able to supply the quantities of Product in the Forecast pursuant to the terms and conditions of the Agreement.
- Purchase Orders; Confirmation. ReShape shall provide to Biorad written purchase orders for Product from time to time ("<u>Purchase Orders</u>"). Every Purchase Order shall include (a) the ordered quantities of Product (by SKU), (b) the delivery date(s), (c) the designation of delivery destination(s), and (d) any other information dictated by the circumstances of the Purchase Order. The specified delivery date for Purchase Orders shall be no less than ninety (90) days after the date of such Purchase Order. Within five (5) business days after its receipt of a Purchase Order placed pursuant to this Section 2.3, Biorad shall acknowledge and accept in writing the receipt of such order, and if no such confirmation is received within such time period, then Biorad shall have been deemed to acknowledge and accept such Purchase Order. Any provision in any Purchase Order, invoice, or similar document furnished by ReShape or Biorad that is in any way inconsistent with the terms and conditions set forth in this Agreement is hereby rejected, unless expressly provided otherwise in writing by the Parties.
- **Delivery.** Biorad shall deliver, or cause to be delivered, the specified quantity Product to ReShape at the delivery destination and by the delivery date specified in the Purchase Order, as acknowledged and accepted by Biorad. Shipments of Product by Biorad shall be Incoterms (2020) EXW-Biorad's Facility. Title to and risk of loss of Product shall pass from Biorad to ReShape upon Biorad's tender of the Product to the common carrier selected by ReShape. ReShape shall confirm the quantity of the Product contained in any shipment. Biorad shall report to ReShape the occurrence of any event within or beyond its control that is likely to affect delivery of any order of Product, as promptly as practicable after Biorad becomes aware of the occurrence of such event.

2.5 **Supply Interruption**. If Biorad fails to deliver to ReShape on a timely basis the full amount of Product under a Purchase Order accepted by Biorad pursuant to Section 2.3 (a "<u>Supply Interruption</u>"), Biorad agrees to meet with ReShape as reasonably requested by ReShape to discuss in good faith appropriate actions to remedy and/or minimize the impact of the Supply Interruption. In any event Biorad shall use commercially reasonable efforts to cooperate with ReShape in taking all actions that the Parties deem reasonable in order to remedy such Supply Interruption as soon as possible.

### **ARTICLE 3**

### PRICE, INVOICE AND PAYMENT

- 3.1 **Price**. The price for each Product to be supplied by Biorad to ReShape under this Agreement is set forth on Exhibit A (the "Price").
- 3.2 **Invoice.** Biorad shall provide to ReShape a written invoice upon shipment of each Product by Biorad.
- 3.3 **Payments**. All payments due hereunder to Biorad shall be paid in U.S. dollars not later than thirty (30) days following ReShape's receipt of the applicable invoice, unless such shipment of Product is rejected under the provisions of Section 4.3. All payments due hereunder shall be made by wire transfer to an account designated by Biorad.
- 3.4 **Taxes**. ReShape shall pay for any and all taxes, duties, levies, imposts, assessments and other similar charges (including any related interest, penalties and other liabilities related thereto) imposed upon or with respect to or measured by the sale of or delivery by Biorad to ReShape of a Product under this Agreement.

### **ARTICLE 4**

### QUALITY CONTROL; ACCEPTANCE AND REJECTION

**Quality Control**. All Product manufactured for and/or supplied to ReShape by Biorad hereunder shall be manufactured in accordance with the Product Specifications and cGMP requirements. Biorad shall maintain and follow quality control and testing procedures in a manner consistent with its customary practices (the "Quality Control Procedures"). Biorad shall procure and provide evidence to ReShape of a Certificate of Registration of Biorad's quality management system in accordance with ISO 13485:2016 and EN ISO 13485:2016.

Quality Audits. Biorad shall maintain all quality control documentation for each batch of Product for two (2) years after Biorad delivers such Product to ReShape, and shall make available to ReShape copies of such records upon request. After such time period, Biorad shall notify ReShape prior to the destruction of any record retained under this Section 4.2, and, at ReShape's request, shall transfer such quality control documentation to ReShape. Notwithstanding the foregoing, upon expiration or termination of this Agreement, at ReShape's expense, Biorad shall transfer all such quality control documentation to ReShape, and Biorad shall not be obligated to retain copies of any such quality control documentation transferred to ReShape. During the Term and not more than once per calendar year, ReShape shall have the right, at its sole cost and expense, during normal business hours and upon reasonable advance written notice to Biorad, to have its employees and agents visit the Biorad Facilities to assess their compliance with the terms of this Agreement, including the Quality Control Procedures; provided that, ReShape may undertake more frequent visits if previous visits reveal, or ReShape otherwise has a reasonable basis to believe there has been, quality incidents or non-compliance with applicable cGMP standards, applicable Law, or this Agreement or the Quality Agreement. For purposes of clarification, when onsite performing such audits, ReShape's employees and agents shall be responsible for its employees and agents compliance with the foregoing. Observations and conclusions of ReShape's audits will be issued to, and promptly discussed with Biorad. If ReShape reasonably considers corrective actions are needed, ReShape shall recommend corrective actions. Costs for implementing these, or other associated, corrective actions will be discussed in good faith by both Parties.

### 4.3 Inspection, Acceptance and Rejection.

- ReShape shall, as soon as reasonably practicable, and in any case within ten (10) business days of receiving any shipment of Product, inspect the Product for any Obvious Defect from the receipt of Product delivered to ReShape hereunder. ReShape may reject any Non-Conforming Product due to an Obvious Defect delivered under this Agreement by giving written notice of such Non-Conforming Product to Biorad promptly and in any case within ten (10) business days of ReShape's receipt of such shipment of Product. Such written notice shall include a reasonably detailed written statement of its reasons for rejection and, where appropriate, Product samples demonstrating the proposed non-conformance. If ReShape fails to so notify Biorad of any Non-Conforming Product due to an Obvious Defect within such ten (10) business day period, ReShape will be deemed to have accepted such quantities of Product not otherwise rejected, subject to Section 4.3(b), and shall not be entitled to any remedies for such Obvious Defects under this Agreement, including but not limited to this Section 4.3 and Article 7.
- (b) If, after ReShape's initial acceptance or deemed acceptance, ReShape determines that any such quantity of Product delivered hereunder is a Non-Conforming Product due to Latent Defects not reasonably discoverable at the time of receipt, ReShape may revoke its acceptance with respect to such quantity of Non-Conforming Product by providing written notice to Biorad of such revocation. ReShape shall have ten (10) business days from the date of discovery that the Product is non-conforming due to a Latent Defect, to reject such Product (in whole or in part) by written notice thereof to Biorad. If ReShape fails to so notify Biorad within such ten (10) business day time period, ReShape shall be deemed to have accepted such delivery of Product and shall not be entitled to any remedies for such Latent Defect under this under this Agreement, including but not limited to this Section 4.3 and Article 7.
- (c) Upon receipt of notice of rejection from ReShape, if Biorad agrees with ReShape's determination of Non-Conforming Product, Biorad shall use commercially reasonable efforts to provide a replacement shipment for the Non-Conforming Product rejected by ReShape. ReShape shall not be required to pay for Product (including transportation and destruction costs) that ultimately is agreed or found to be a Non-Conforming Product as long as the root cause of this Non-Conforming Product is not caused by any acts or omissions of ReShape or its Affiliates.

- (d) If Biorad does not accept ReShape's assertion that the rejected Product is Non-Conforming Product, Biorad shall provide written notice to ReShape that the rejection is not accepted, and state the reasons for its conclusion within fifteen (15) business days after receipt of ReShape's notice of rejection pursuant to Section 4.3(a) or 4.3(b). Both Parties shall work in good faith to find a mutually acceptable solution. If the Parties fail to find a mutually acceptable solution within twenty (20) business days after ReShape receives Biorad's notice under this Section 4.3(d), ReShape shall provide a representative sample of the Product from the relevant shipment, and Biorad shall provide related quality control documentation, to a mutually agreed independent Third Party. Both Parties shall be bound by the determination of such independent Third Party, which determination shall be made in writing and shall include reasoning, and the Party against which the determination is made shall bear all costs associated with such Third Party determination, including those of the Party in whose favor the Third Party determination is given.
- 4.4 **Quality Agreement**. The Parties shall negotiate in good faith and enter into a quality agreement establishing the quality requirements for Product (the "Quality Agreement"). To the extent there are any conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail except with respect to quality matters.

### **REGULATORY OBLIGATIONS**

- Regulatory Activities. Biorad shall obtain and maintain at all times during the Term all site licenses and other Regulatory Approvals as required for Biorad to manufacture the Products in accordance with applicable Law. Biorad shall provide all regulatory and technical information relating to the manufacture and supply of the Products as reasonably requested by ReShape. Biorad shall use commercially reasonable efforts to assist ReShape with the transfer of registration of Product from Biorad to ReShape, and in obtaining any necessary or desirable Regulatory Approvals. Biorad shall notify ReShape immediately of any warning, citation, claim, lawsuit or proceeding issued or instituted by any federal, foreign, state, local or foreign governmental entity or Regulatory Authority against Biorad or of any revocation of any license or permit issued to Biorad, to the extent that such occurrences are related to or could impact Biorad's performance hereunder. Biorad shall promptly provide ReShape with copies of the relevant portions of any documents provided or received by Biorad in connection with the matters set forth in this Section 5.1.
- 5.2 **Change in Manufacturing Process**. Biorad shall promptly give written notice to ReShape if Biorad implements any change in the materials (including sources thereof), equipment, process or procedures used to manufacture or test Product that would require notification of, or approval by, any Regulatory Authority and/or amendments to any existing Regulatory Approvals or pending applications therefor. Biorad shall disclose all proposed changes in such manufacturing and testing materials, equipment, process or procedure to ReShape, and the Parties shall revise the relevant Product Specifications accordingly, if necessary.
- 5.3 **Records**. Biorad shall keep complete, accurate and authentic accounts, notes, data and records pertaining to the manufacture, processing, testing, storage, and distribution of the Product in accordance with applicable Law. Biorad shall use commercially reasonable efforts to maintain and store such records in a manner to prevent loss, theft or deterioration. Biorad shall retain such records for twelve (12) months following the date of manufacture, or such longer period of time required by applicable Laws, and shall make available to ReShape copies of such records upon request. After such time period, Biorad shall notify ReShape prior to the destruction of any record retained under this Section 5.3 and, at ReShape's request, shall transfer such records to ReShape. Notwithstanding the foregoing, upon expiration or termination of this Agreement, at ReShape's expense, Biorad shall transfer all such records to ReShape, and Biorad shall not be obligated to retain copies of any such records transferred to ReShape.

- Recall. In the event a Product is recalled, Biorad shall provide ReShape with such assistance in connection with such recall as may reasonably be requested by ReShape. All costs and expenses associated with any recall or withdrawal of Product shall be borne by ReShape; provided, however, that, to the extent that such recall or withdrawal of Product is caused by breach of any of the warranties set forth in Section 6.2, Biorad shall (a) upon mutual agreement of the Parties that Biorad has breached a warranty, subject to Section Error! Reference source not found., at ReShape's option, (i) reimburse ReShape for the amounts paid by ReShape to Biorad for the recalled or withdrawn Product, or (ii) provide to ReShape at no further cost to ReShape sufficient Product to enable ReShape to supply to its customers Products to replace those that are the subject of the recall or withdrawal. and (b) reimburse ReShape the reasonable out-of-pocket costs of (i) effectuating the communications and logistics of the recall, withdrawal or removal from ReShape's customers and patients and (ii) transporting such replacement Products to ReShape's customers; provided that, in each case, ReShape provides Biorad with accurate and complete copies of supporting documentation related to such out-of-pocket costs.
- 5.5 **Safety Notifications**. In case a Product is potentially deviating from the Product Specifications, or under any other circumstance where such Product might cause, or already has caused harm to a patient, user or other person, each Party shall notify the other Party in writing (such writing, a "**Safety Notification**"), irrespective of the time or location of detection of the potentially faulty Product, as soon as the respective Party has knowledge of such. This Agreement shall not prevent ReShape from reporting any medical device incident as required by any applicable Law. Safety Notifications and any other complaints on the Products are to be effected to the following address:

Biorad:	ReShape:
	ReShape Lifesciences Inc.
	Attn: VP Regulatory, Clinical and Quality
	18 Technology Drive, Suite 110
	Irvine, CA 92618
	Email: dgal@reshapelifesci.com
	Tel: 949-481-4789

### **REPRESENTATIONS AND WARRANTIES**

- 6.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party as follows:
- (a) **Due Authorization and Enforcement of Obligations**. It has the power and authority and the legal right to enter into this Agreement to perform its obligations hereunder, and has taken all necessary action on its part to authorize the performance of such obligations. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.
- (b) **No Conflict**. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable Law and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of such Party.

- 6.2 **Warranties of Biorad**. Subject to Section 6.3, Biorad represents, warrants and covenants, as of the Effective Date and at all times during the Term:
- (a) all Product supplied by Biorad to ReShape hereunder shall (i) at the time of delivery, conform to the Product Specifications; (ii) be manufactured in compliance with this Agreement, cGMP, and applicable Law; and (iii) not be adulterated or misbranded within the meaning of the FD&C Act.
- (b) it has obtained all Regulatory Approvals required by applicable Law for the performance of its obligations under this Agreement.
- 6.3 <u>Disclaimers of Warranty.</u> EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT (INCLUDING ANY EXHIBIT, SCHEDULE OR ATTACHMENT HERETO), BIORAD MAKES, NO WARRANTY OF ANY KIND, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, DESIGN, NON-INFRINGEMENT, SUITABILITY OF QUALITY AND FITNESS FOR A PARTICULAR PURPOSE, OR ARISING FROM A COURSE OF DEALING OR USAGE OR TRADE PRACTICE, WITH REGARD TO ANY PRODUCT DELIVERED HEREUNDER, WHETHER USED ALONE OR IN COMBINATION WITH OTHER SUBSTANCES.

### **INDEMNIFICATION**

- 7.1 **Indemnification by Biorad**. Subject in all respect to the limitations set forth in Section **Error! Reference source not found.**, Biorad hereby agrees to indemnify, defend and hold harmless ReShape, its Affiliates and contractors and their respective directors, officers, employees, and permitted assigns (each, a "ReShape Indemnified Person"), from and against any and all costs, expenses, liabilities, damages, losses and harm (including reasonable legal expenses and attorneys' fees regardless of outcome) ("Damages") arising out of or resulting from any Third Party suits, claims, actions, or demands (collectively, "Claims"), to the extent arising or resulting from (a) the gross negligence or willful misconduct of Biorad in the course of Biorad's manufacture or supply of the Product, and (b) Biorad's breach of its obligations, warranties, or representations under this Agreement, except in each case to the extent that any such Claim is the consequence of the negligence or willful misconduct of such ReShape Indemnified Person or of ReShape's breach of its obligations, warranties or representations under this Agreement.
- 7.2 **Indemnification by ReShape**. Subject in all respect to the limitations set forth in Section **Error! Reference source not found.**, ReShape agrees to indemnify, defend and hold harmless Biorad and its officers, directors, employees, and permitted assigns (each, an "<u>Biorad Indemnified Person</u>"), from and against any and all Damages arising out of or resulting from any Claims, to the extent arising or resulting from (a) Biorad's manufacture or supply of the Product, and (b) ReShape's breach of its obligations, warranties, or representations under this Agreement, except in each case to the extent that any such Claim is the consequence of the negligence or willful misconduct of such Biorad Indemnified Person or of Biorad's breach of its obligations, warranties or representations under this Agreement.
- 7.3 Limitation on Damages and Disclaimer. WITH THE EXCEPTION FOR INTENTIONAL MISCONDUCT OR GROSS NEGLIGENCE OF SUCH PARTY, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, COLLATERAL, EXEMPLARY, PUNITIVE, OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF INCOME, PROFIT OR SAVINGS, OF ANY PARTY, INCLUDING THIRD PARTIES, REGARDLESS OF THE FORM OF THE ACTION OR THE THEORY OF RECOVERY, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

OTHER THAN WARRANTIES SET FORTH HEREIN, EACH PARTY MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADEMARK, SOFTWARE, TRADE SECRET, TANGIBLE RESEARCH PROPERTY, INFORMATION OR DATA LICENSED OR OTHERWISE PROVIDED TO THE OTHER PARTY HEREUNDER AND HEREBY DISCLAIMS THE SAME.

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO OTHER PARTY HEREUNDER UNDER ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION, BREACH OF THIS AGREEMENT FOR AN AMOUNT IN EXCESS OF THE ACTUAL AMOUNTS PAID HEREUNDER TO LICENSOR BY LICENSEE. EITHER PARTY'S MAXIMUM LIABILITY TO THE OTHER PARTY HEREUNDER IN THE AGGREGATE WILL NOT EXCEED THE AMOUNTS PAID BY RESHAPE TO BIORAD.

7.4 **Insurance**. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Parties upon request.

### **ARTICLE 8**

### **CONFIDENTIALITY**

- 8.1 **Confidentiality**. Except to the extent expressly authorized by this Agreement or otherwise agreed to in writing by the Parties, each Party agrees that, for the Term and for seven (7) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information (as defined in the Transition Services Agreement) furnished to it (a "Receiving Party") by the other Party (the "Disclosing Party") pursuant to this Agreement or the Confidentiality Agreement, except that the foregoing shall not apply to any information for which the Receiving Party can demonstrate, by competent proof, that it:
- (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Receiving Party to whom it disclosed such information;
- (b) was known to, or was otherwise in the possession of, the Receiving Party prior to its disclosure to the Receiving Party and was not subject to an obligation of confidentiality;
- (c) is disclosed to the Receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party; or
- (d) is independently developed by or on behalf of the Receiving Party or any of its Affiliates outside of this Agreement, as evidenced by its written records, without use of the Confidential Information.
- Authorized Disclosure. The Receiving Party may disclose the Disclosing Party's Confidential Information if required to do so under applicable Law, a court order or other governmental order or by obligations pursuant to any listing agreement with or rules of any securities exchange or trading market on which securities of such Party or any of its affiliates are listed, provided that the Receiving Party (to the extent allowed by the applicable Law): (a) provides the Disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) affords the Disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure and (c) if the Disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the Receiving Party is required to disclose as advised by the Receiving Party's legal counsel. In the event of a limited disclosure of the Disclosing Party's Confidential Information that is required by law or regulation, the Receiving Party shall continue to treat such disclosed information as the Disclosing Party's Confidential Information for all other purposes and subject to the other terms and conditions of this Agreement.

8.3 <b>Return or Destruction of Confidential Information.</b> Upon termination or expiration of the Agreement, or upon written requ	uest of the
Disclosing Party, a Receiving Party will promptly return to the Disclosing Party or destroy all documents, notes and other tangible materials re	presenting
he Disclosing Party's Confidential Information and all copies thereof; provided, however, that each Party may retain a single archival copy of	f the other
Party's Confidential Information for the sole purpose of facilitating compliance with the surviving provisions of this Agreement.	

### TERM AND TERMINATION

9.1	Term.	This	Agreement	shall	commence	on	the	Effective	Date	and	shall	expire	on	<b>,</b>	unless	earlier
terminated as p	ermitted 1	under	this Article	9 (the	" <u>Term</u> ").											

- 9.2 **Termination by ReShape**. ReShape may terminate this Agreement upon at least thirty (30) days written notice to Biorad; provided that, ReShape shall be responsible for any costs incurred by Biorad for raw materials or components purchased, or works-in-progress made, by Biorad or its Affiliates in accordance with Purchase Orders provided by ReShape prior to the effective date of such termination.
- 9.3 **Termination for Material Breach**. In the event of a material breach of this Agreement by a Party, the Party claiming the breach shall give written notice of such breach to the other Party, which shall have thirty (30) calendar days to cure such breach. In the event of such cure, the notice of breach shall be rescinded. If, however, the breach is not cured during such thirty (30) calendar day period, the Party claiming the breach shall have the right to terminate this Agreement effective on a date of termination prior to the end of the relevant service period established by the non-breaching Party.
- 9.4 **Termination for Bankruptcy**. Either Party may immediately terminate this Agreement upon the occurrence of either of the following: (a) the entry of a decree or order for relief by a court having jurisdiction in the premises in respect of the other Party in an involuntary case under any applicable national, federal, or state insolvency or other similar law, and the continuance of any such decree or order unstayed and in effect for a period of sixty (60) consecutive days; or (b) the filing by the other Party of a petition for relief under any applicable national, federal, or state insolvency or other similar law.
  - 9.5 **Termination for Mutual Consent.** This Agreement may be terminated by the mutual written consent of Biorad and ReShape.
  - 9.6 **Consequences of Termination**.
- (a) Upon the expiration or early termination of this Agreement, (i) Biorad shall promptly cease all performance under this Agreement, (ii) each of the Parties shall promptly return or destroy all Confidential Information of the other Party in connection with this Agreement pursuant to Section 8.3, and (iii) ReShape shall make any accrued and unpaid payment to Biorad as required pursuant to the terms of this Agreement.

- (b) Upon the expiration or early termination of this Agreement, ReShape shall also: pay Biorad for work-in-progress inventory of the Products pursuant to Purchase Orders placed prior to, but not completed by, the date of expiration or early termination of this Agreement, including the cost of producing such work-in-progress inventory.
- 9.7 **Surviving Obligations**. Termination or expiration of this Agreement shall not (a) affect any other rights of either Party which may have accrued up to the date of such termination or expiration or (b) relieve ReShape of its obligation to pay to Biorad sums due in respect of product delivered prior to termination or expiration of this Agreement (subject to ReShape's acceptance pursuant to Section 4.3). The provisions of Sections **Error! Reference source not found.**, 9.6, 9.7 and Articles 1, 7, 8 and 10 shall survive the termination or expiration of this Agreement.

### **MISCELLANEOUS**

- Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to an event of Force Majeure Event. For purposes of this Agreement, "Force Majeure Event" is defined as causes beyond the control of the applicable Party, including acts of God, war, civil commotion, acts of aggression, sabotage, embargoes, fires, floods, drought, earthquakes, storms, accidents, explosions, utility failures, national labor disturbances, strikes, riots, delays or errors by shipping companies, changes in law, national health emergencies, destruction, damage or appropriations of property, government requirements, civil or military authorities or terrorism or the threat of any of the foregoing. In such event, the affected Party shall notify the other Party as soon as reasonably practicable of such inability and of the period for which such inability is expected to continue. The affected Party thereupon shall not be excused from such of its obligations under this Agreement, but such obligations shall be suspended for so long as it is disabled from performing by such Force Majeure Event. The affected Party shall use commercially reasonable efforts to minimize the duration of any Force Majeure Event. When a Force Majeure Event arises, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution. Neither Party shall be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or any other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event.
- Notices. Any notice or other communication required or permitted to be delivered to any Party under this Agreement shall be in writing and shall be deemed properly delivered, given and received when delivered (by hand, by registered mail, by courier or express delivery service or by email) to the address or facsimile telephone number or e-mail address set forth beneath the name of such Party below (or to such other address or e-mail address as such Party shall have specified in a written notice given to the other Parties):

if to ReShape:

ReShape Lifesciences Inc.
18 Technology Drive, Suite 110
Irvine, CA 92618
Attention: President and CEO
E-mail: phickey@reshapelifesci.com

with a copy to:

Fox Rothschild LLP 33 South Sixth Street, Suite 3600 Minneapolis, MN 55402 Attn: Brett Hanson

Email: bhanson@foxrothschild.com

if to Biorad:

Mr. Hemant Joshi Biorad Medisys Private Limited Survey No. 48/3 & 48/7, Pashan Sus Road, Sus Village, Taluka Mulshi, Pune Maharashtra 411021, India Email: Hemant.joshi@bioradmedisys.com

with a copy to:

Jitendra M Hegde Biorad Medisys Private Limited Survey No. 48/3 & 48/7, Pashan Sus Road, Sus Village, Taluka Mulshi, Pune Maharashtra 411021, India Emaill: jmhegde@bioradmedisys.com

- Counterparts. This Agreement may be executed in several counterparts, each of which shall constitute an original and all of which, when taken together, shall constitute one agreement. Any signature page hereto delivered by facsimile machine or by e-mail (including in portable document format (pdf), as a joint photographic experts group (jpg) file, or otherwise) shall be binding to the same extent as an original signature page, with regard to any agreement subject to the terms hereof or any amendment thereto and may be used in lieu of the original signatures for all purposes. Any Party that delivers such a signature page agrees to later deliver an original counterpart to any Party that requests it.
- 10.4 **Governing Law**. This Agreement shall be construed in accordance with, and governed in all respects by, the internal laws of the State of Delaware (without giving effect to principles of conflicts of laws).
- 10.5 **No Third Party Beneficiaries**. This Agreement is not intended to confer upon any Person other than the Parties hereto any rights or remedies hereunder.
- Assignment. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) each Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; and (b) either Party may assign this Agreement without such consent in connection with the acquisition (whether by merger, consolidation, sale or otherwise) of such Party or of that part of such Party's business to which this Agreement relates, as long as such Party provides written notice to the other Party of such assignment and the assignee thereof agrees in writing to assume and be bound as the assigning Party hereunder. Any purported assignment in violation of this Section 10.66 shall be void. Subject to the preceding sentence, this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns.

- 10.7 **Entire Agreement; Amendment**. This Agreement, the License Agreement, and the Exhibits attached hereto constitute the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior written and oral agreements between the Parties regarding the subject matter of this Agreement may not be amended, modified, altered or supplemented other than by means of a written instrument duly executed and delivered on behalf of each of the Parties hereto.
- Construction. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, and the use of any gender will be applicable to all genders. Unless expressly provided otherwise, references to Sections are references to Sections of this Agreement. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used in this Agreement will mean including, without limiting the generality of any description preceding such term. No rule of strict construction will be applied against either Party.
- Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term.
- 10.10 **Headings**. The underlined headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.
- 10.11 **Waiver.** No waiver of any term or condition of this Agreement shall be valid or binding on either Party unless agreed in writing by the Party to be charged. The failure of either Party to enforce at any time any of the provisions of the Agreement, or the failure to require at any time performance by the other Party of any of the provisions of this Agreement, shall in no way be construed to be a present or future waiver of such provisions, nor in any way affect the validity of either Party to enforce each and every such provision thereafter.

[Remainder of page intentionally left blank]

The Parties have caused this Agreen	ent to be executed and delivered as of the date first written above.
	BIORAD MEDYSIS, PVT. LTD
	By:
	Name:
	Title:
	ReShape Lifesciences Inc.
	By:
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### ReShape Lifesciences<sup>®</sup> Signs Exclusive License Agreement With Biorad Medisys for Obalon<sup>®</sup> Gastric Balloon System

Royalty-Bearing License Agreement Covers the Countries in the Indian Subcontinent, Representing Approximately 20% to 25% of the World's Population

**IRVINE, Calif., September 21, 2023** -- ReShape Lifesciences Inc. (Nasdaq: RSLS), the premier physician-led weight loss and metabolic health solutions company, today announced the signing of an exclusive, royalty-bearing license agreement with Biorad Medysis, Pvt. Ltd. (Biorad) to manufacture, commercialize and distribute the Obalon<sup>®</sup> Gastric Balloon System in India, Pakistan, Bangladesh, Nepal, Bhutan, Sri Lanka, and the Maldives. Based in Mumbai, India, Biorad is an established, science-driven medical device manufacturer that has successfully manufactured and sold innovative medical devices in the urology, gastroenterology, orthopedic and neurovascular industries, which is now expanding into the bariatric arena. The license agreement provides \$200,000 in upfront payments from Biorad to ReShape and ongoing license payments of 4% on gross sales of the Obalon Balloon System in the territories.

"This exclusive agreement with Biorad represents the first step towards reintroducing our patented Obalon Balloon System technology to the global marketplace," stated Paul F. Hickey, President and Chief Executive Officer of ReShape Lifesciences. "We believe that Biorad, with decades of experience manufacturing and distributing medical devices in the vast South Asia market, potentially reaching approximately 20% to 25% of the world's population, is an ideal partner to expand the reach of ReShape's Obalon technology. Our non-surgical, minimally invasive, Obalon System was the first swallowable, gas filled balloon system approved by the U.S. Food and Drug Administration, around which we continue to build a strong intellectual property portfolio. We look forward to a fruitful partnership with Biorad, which we expect will lay the groundwork to catalyze the successful relaunch and joint commercialization of the balloon system in markets world-wide."

### About ReShape Lifesciences®

ReShape Lifesciences<sup>®</sup> is America's premier weight loss and metabolic health-solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease. The FDA-approved Lap-Band<sup>®</sup> System provides minimally invasive, long-term treatment of obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. ReShapeCare<sup>TM</sup> is a virtual weight-management program that supports lifestyle changes for all weight loss patients led by board-certified health coaches to help them keep the weight off over time. ReShape Marketplace<sup>TM</sup> is an online collection of quality wellness products curated for all consumers to help them achieve their health goals. The investigational Diabetes Bloc-Stim Neuromodulation<sup>TM</sup> (DBSN<sup>TM</sup>) system utilizes a proprietary vagus nerve block and stimulation technology platform for the treatment of Type 2 diabetes and metabolic disorders. The Obalon<sup>®</sup> balloon technology is a non-surgical, swallowable, gas-filled intragastric balloon that is designed to provide long-lasting weight loss. For more information, please visit www.reshapelifesciences.com.

### **Forward-Looking Safe Harbor Statement**

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those discussed due to known and unknown risks, uncertainties, and other factors. These forward-looking statements generally can be identified by the use of words such as "expect," "plan," "anticipate," "could," "may," "intend," "will," "continue," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include the statements regarding our expectations for the successful relaunch of the Obalon Balloon technology. These and additional risks and uncertainties are described more fully in the company's filings with the Securities and Exchange Commission, including those factors identified as "risk factors" in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. We are providing this information as of the date of this press release and do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise, except as required by law.

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