

**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): October 26, 2023

bluebird bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35966
(Commission
File Number)

13-3680878
(IRS Employer
Identification Number)

455 Grand Union Boulevard,
Somerville, MA
02145
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (339) 499-9300

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	BLUE	The Nasdaq Stock Market LLC

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

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

Item 1.01. Entry into a Material Definitive Agreement.

On October 26, 2023, bluebird bio, Inc. (the “Company”) entered into an asset purchase agreement (the “PRV Transfer Agreement”) with Novartis Pharma AG (“Buyer”), pursuant to which the Company agreed to sell to Buyer a Rare Pediatric Disease Priority Review Voucher (“PRV”), if received, in connection with the potential approval of lovetibeglogene autotemcel (lovo-cel) with a proposed indication for patients with sickle cell disease 12 years and older with a history of vaso-occlusive events. Under the terms of the PRV Transfer Agreement, rights to the PRV would transfer to Buyer and the Company would receive \$103 million upon closing of the sale, which is contingent upon the U.S. Food and Drug Administration’s (“FDA”) approval of the biologics license application (“BLA”) for lovo-cel and granting of the PRV.

The PRV Transfer Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations.

Closing of the transaction remains subject to the approval of the BLA for lovo-cel and receipt of a PRV from the FDA, as well as customary closing conditions.

The foregoing description of the PRV Transfer Agreement does not purport to be complete and is qualified in its entirety by the full text of the PRV Transfer Agreement, a copy of which is filed as Exhibit 2.1 to this Current Report on Form 8-K and incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements, including our statements regarding the closing of the sale of the Company’s PRV, if received, as well as statements regarding the expected timing relating to its potential regulatory approval of lovo-cel and expectations regarding the receipt of a PRV upon potential approval of lovo-cel. Such forward-looking statements are based on historical performance and current expectations and projections about the Company’s future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. No forward-looking statement can be guaranteed. Forward-looking statements in this Current Report on Form 8-K should be evaluated together with the many risks and uncertainties that affect the Company’s business, particularly those identified in the risk factors discussion in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, as updated by subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. These risks include, but are not limited to: the risk that the Company may not receive a PRV upon potential approval of lovo-cel or that lovo-cel may not be approved in the anticipated timeframe or at all; the Company may encounter additional delays in the development of its programs, including the imposition of new clinical holds, which may impact its ability to meet expected timelines and increase its costs; the internal and external costs required for the Company’s ongoing and planned activities, and the resulting impact on expense and use of cash, has been and may in the future be, higher than expected, which has caused the Company, and may in the future cause it, to use cash more quickly than it expects or change or curtail some of its plans or both; the Company’s expectations as to expenses, cash usage and cash needs may prove not to be correct for other reasons such as changes in plans or actual events being different than its assumptions; the risk that the efficacy and safety results from the Company’s prior and ongoing clinical trials will not continue or be seen in additional patients treated with its product candidates; the risk of insertional oncogenic or other reportable events associated with lentiviral vector, drug product, or myeloablation; and the risk that any one or more of the Company’s products or product candidates, including lovo-cel, will not be successfully developed, approved or commercialized. The forward-looking statements included in this Current Report on Form 8-K are made only as of the date hereof and except as otherwise required by applicable law, the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
2.1+	Asset Purchase Agreement, dated as of October 26, 2023, by and between bluebird bio, Inc. and Novartis Pharma AG.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

+ Exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted exhibits upon request by the SEC.

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.

bluebird bio, Inc.

Date: October 30, 2023

By: /s/ Andrew Obenshain
Andrew Obenshain
President and Chief Executive Officer

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this “**Agreement**”) is made and entered into as of October 26, 2023 (the “**Effective Date**”), by and between bluebird bio, Inc., a corporation organized under the laws of Delaware (“**Seller**”), and Novartis Pharma AG, an entity organized under the laws of Switzerland (“**Buyer**”). Buyer and Seller may hereinafter be referred to individually as a “**Party**” and collectively as the “**Parties**”.

RECITALS

WHEREAS, Seller has submitted the Subject BLA to the FDA, which, if approved, may result in the issuance to Seller of the Priority Review Voucher (as defined below);

WHEREAS, Seller and Buyer each (i) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Purchased Assets (as defined below), subject to the issuance of the Priority Review Voucher by the FDA to Seller, all on the terms set forth herein (such transaction, the “**Asset Purchase**”) and (ii) in furtherance thereof, have duly authorized, approved and executed this Agreement and the other transactions contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below); and

WHEREAS, Seller and Buyer desire to make certain representations, warranties, covenants and other agreements in connection with the Asset Purchase as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties agree as follows:

ARTICLE I.
DEFINITIONS

Section 1.01 Certain Definitions. As used in this Agreement, the following terms shall have the meanings indicated below:

(a) “**Action**” means any claim, audit, examination, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, mediation, investigation, hearing, charge, complaint, demand, notice, or proceeding.

(b) “**Affiliate**” means, with respect to any Person, any other Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person, for so long as such control exists, whether such Person is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to “control” another Person if it: (i) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of the entity, or the ability to cause the direction of the management or policies of such entity; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(c) “**Alternative Transaction**” means, other than the transactions contemplated by this Agreement, any sale, assignment, transfer or encumbrance, whether by option, agreement, understanding or other arrangement, of any right, title, or interest in and to the Purchased Assets; provided, that, for the avoidance of doubt, (a) a transaction for the sale, assignment, transfer or encumbrance of any or all of the equity interests of Seller shall not be considered an Alternative Transaction, and (b) a transaction for the sale, assignment or transfer or encumbrance of any or all of the assets of Seller (including any other Priority Review Voucher owned or which subsequently becomes owned by the Seller or its Affiliates but excluding the Purchased Assets) shall not be considered an Alternative Transaction.

(d) “**Approval Letter**” means an approval letter issued by the FDA approving the Subject BLA.

(e) “**BLA**” means a human biologics license application submitted under Section 351(a) of the Public Health Service Act.

(f) “**Business Day**” means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in each of New York, New York, United States, Cambridge, Massachusetts, United States and Basel, Switzerland.

(g) “**Confidential Information**” means (i) any and all confidential and proprietary information, including but not limited to, data, results, conclusions, know-how, experience, financial information, plans and forecasts, that may be delivered, made available, disclosed or communicated by a Party or its Affiliates or their respective Representatives to the other Party or its Affiliates or their respective Representatives, related to the subject matter hereof or otherwise in connection with this Agreement and (ii) the terms, conditions and existence of this Agreement. “Confidential Information” will not include information that (A) at the time of disclosure, is generally available to the public, (B) after disclosure hereunder, becomes generally available to the public, except as a result of a breach of this Agreement by the recipient of such information, (C) becomes available to the recipient of such information from a Third Party that is not legally or contractually prohibited by the disclosing Party from disclosing such Confidential Information; or (D) was independently developed by or for the recipient of such information without the use of or reference to any of the Confidential Information of the disclosing Party or its Affiliates, as evidenced by the recipient’s contemporaneous written records. Notwithstanding anything herein to the contrary, all Confidential Information included within the Purchased Assets (which, for the avoidance of doubt, shall not include any confidential and proprietary information relating to the product to which the Subject BLA relates) shall constitute Confidential Information of Buyer from and after the Closing Date.

(h) “**Contract**” means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(i) “**Encumbrance**” means any lien, pledge, charge, mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, right of negotiation or refusal, lease, security interest, encumbrance, adverse claim, interference or restriction on use, ownership or transfer; provided, that the requirement to pay the Priority Review Fee shall not be considered an Encumbrance.

(j) “**FDA**” means the United States Food and Drug Administration.

(k) “**FDA Notification Package**” means, collectively, executed versions of the joint FDA acknowledgement letter, Seller transfer acknowledgement letter and Buyer transfer acknowledgment letter in the forms set forth in Exhibits B, C, and D, respectively, in each case, with respect to the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA in accordance with Section 3.04.

(l) “**FDCA**” means the United States Federal Food, Drug, and Cosmetic Act.

(m) “**Fraud**” means common law fraud with respect to the making of the representations or warranties in Article IV or Article V hereof, as applicable.

(n) “**Governmental Entity**” means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental, private body or arbitral body exercising any executive, legislative, judicial, quasi-judicial, regulatory, taxing, importing, administrative or other governmental or quasi-governmental authority.

(o) “**Judgment**” means any orders, writs, injunctions, awards, judgments, settlements, stipulations, determinations, and decrees entered by or with any Governmental Entity.

(p) “**Knowledge**” means, with respect to Seller, the actual knowledge of Leslie Wilder (Head of Regulatory Science), Christopher Krawtschuk (Chief Financial Officer), Andrew Obenshain (Chief Executive Officer), Joe Vittiglio (Chief Business and Legal Officer) and Rich Colvin (Chief Medical Officer), after reasonable inquiry.

(q) “**Legal Requirements**” means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders or Judgment applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, as applicable, any obligations, responsibilities, requirements, parameters and conditions relating to the Priority Review Voucher set forth in (i) the Approval Letter, (ii) any other correspondence received by Seller or its Affiliates from the FDA regarding the Priority Review Voucher, (iii) Section 529 of the FDCA (21 U.S.C. § 360ff), or (iv) in the FDA’s Draft Guidance, “Rare Pediatric Disease Priority Review Vouchers – Guidance for Industry” (July 2019).

(r) “**Liabilities**” means all debts, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any Legal Requirement, Action or any Contract.

(s) “**Market**” or “**Marketing**” means to market a drug within the meaning of Section 529(e)(1) of the FDCA.

(t) “**Notice of Intent to Use**” means notification to the FDA not later than ninety (90) days prior to the submission of a human drug application of the intent to use the Priority Review Voucher to obtain Priority Review of a human drug application, as described in 21 U.S.C. § 360ff(b)(4)(B)(i).

(u) “**Order**” means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.

(v) “**Person**” means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

(w) **“Priority Review”** means priority review and action on a human drug application by the FDA in accordance with the timelines set forth by the FDA for “priority review” applications in the then-current Prescription Drug User Fee Act goals letter, as described in FDA Draft Guidance, “Rare Pediatric Disease Priority Review Vouchers – Guidance for Industry” (July 2019).

(x) **“Priority Review Fee”** has the meaning set forth in Section 10.07.

(y) **“Priority Review Voucher”** means a rare pediatric disease priority review voucher that may be issued by the FDA, pursuant to 21 U.S.C. 360ff(b)(1), to Seller in connection with a potential, future approval of the Subject BLA, as would be evidenced in an Approval Letter of the Subject BLA (if the Subject BLA is approved), if granted.

(z) **“Purchased Assets”** means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements with respect thereto afforded to the holder of the Priority Review Voucher.

(aa) **“Regulatory Change”** means any (i) new Legal Requirement, amendment, change or supplement to any then-existing Legal Requirement enacted, adopted or approved by any Governmental Entity in the United States, or (ii) term or condition imposed on the Priority Review Voucher that is not generally imposed on priority review vouchers under the FDCA as of the Effective Date, that in either case (i) or (ii) has been enacted, adopted, approved or imposed between the Effective Date and the Closing Date (except as set forth in Section 4.11 hereof) and adversely impacts the manner in which Buyer would be able to use, receive, hold, transfer or otherwise exploit the Priority Review Voucher, if granted.

(bb) **“Representative”** means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(cc) **“Subject BLA”** means BLA Number 125788 for lovetibeglogene autotemcel for patients with Sickle Cell Disease (SCD) 12 years and older with a history of vaso-occlusive events.

(dd) **“Tax”** or **“Taxes”** means any federal, state, local or foreign income, gross receipts, branch profits, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, ad valorem, value added, alternative or add-on minimum or estimated tax or other tax of any kind whatsoever, including any interest, penalty or addition thereto, whether disputed or not.

(ee) **“Tax Return”** shall mean any return, declaration, report, claim for refund or information return or statement of any kind relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof, filed or required to be filed with any Governmental Entity.

(ff) **“Third Party”** means any Person other than a Party and such Party’s Affiliates.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.01 shall have the meanings assigned to such terms in this Agreement.

**ARTICLE II.
PURCHASE AND SALE**

Section 2.01 Purchase and Sale; No Assumed Liabilities.

(a) Upon the terms and subject to the conditions of this Agreement, including, without limitation, issuance of the Approval Letter and granting to Seller the Priority Review Voucher, Buyer agrees to purchase from Seller, and Seller agrees to sell, transfer, convey, assign and deliver to Buyer, at the Closing all of Seller's right, title and interest in, to and under the Purchased Assets, in each case free and clear of all Encumbrances.

(b) For the avoidance of doubt, (i) the sale, assignment, transfer and conveyance of the Purchased Assets from Seller to Buyer shall not include the transfer, conveyance or assumption of any Liabilities from Seller to Buyer, and (ii) Buyer shall not assume or be liable for any Liabilities of Seller or its Affiliates (fixed, contingent or otherwise, and whether or not accrued), including Liabilities relating to the Purchased Assets (other than such obligations as are imposed generally by applicable Legal Requirements solely on the holder of the Priority Review Voucher in respect of its use or transfer following the sale thereof pursuant to this Agreement, including, without limitation, the Priority Review Fee and any user fees required to be paid in connection with the submission of a human drug application or BLA for which the applicant seeks to redeem the Priority Review Voucher) (such Liabilities, "**Excluded Liabilities**"). Seller shall be solely responsible for all such Excluded Liabilities.

Section 2.02 Purchase Price. The total consideration (the "**Purchase Price**") to be paid by Buyer to Seller for all of the Purchased Assets shall be One Hundred and Three Million Dollars (U.S. \$103,000,000.00) due and payable upon the Closing Date.

Section 2.03 Method of Payment. Payment of the Purchase Price to Seller shall be made in cash by wire transfer of immediately available funds to a bank account specified by Seller in writing to Buyer in the form of Valid Account Details no later than five (5) Business Days prior to the Closing Date. "**Valid Account Details**" means, with respect to any bank account, the valid (a) name of bank, (b) bank's address, (c) account number, (d) account name and (e) ABA/Routing number.

Section 2.04 Tax Withholding.

(a) In the event any payments to be made to Seller under this Agreement are subject to withholding tax under applicable Legal Requirements, including extra-territorial taxation, Buyer shall be authorized to deduct the withholding tax from the payments, and shall pay all such withholding tax to the relevant tax authority, so that only the correspondingly reduced amount of payments (i.e. the full amount payable less withholding tax) is paid out to Seller. Before making any such deduction or withholding, Buyer shall use commercially reasonable efforts to provide to Seller notice of Buyer's intention to make such deduction and withholding and, in reasonable detail, an explanation of the law and method of calculation for the proposed deduction or withholding in order to provide Seller an opportunity to obtain reduction of or relief from such deduction or withholding. Buyer shall provide Seller with proof of the withholding tax payment.

(b) Buyer and Seller shall make all reasonable efforts to obtain relief or reduction of withholding tax under the applicable tax treaties, including but not limited to the submission or issuance of requisite forms and information. If a special procedure is required for treaty relief by any Legal Requirement, a treaty relief based on a tax treaty will only be taken into account if Seller submits any exemption certificate requested by Buyer to Buyer in accordance with Legal Requirements on or prior to the time of the payment to Seller.

(c) Any refunds of withholding taxes that are granted to Seller by the competent tax authority and which would cause Seller to receive payments in excess of that which Buyer would owe under this Agreement, including related interest, shall be paid to Buyer by Seller.

**ARTICLE III.
CLOSING**

Section 3.01 Closing. The transactions set forth in Section 3.02 shall be effected remotely via the electronic exchange of documents and signatures at 9:00 a.m. Eastern Time on the third (3rd) Business Day after all of the conditions set forth in Article VI have been satisfied or waived (other than those conditions which, by their terms, are intended to be satisfied at the Closing, but subject to satisfaction or waiver of such conditions) (provided, that, if such date would otherwise fall on a date between December 27, 2023 and December 29, 2023, such transactions shall be effected on January 2, 2024), or at such other time and place as the Parties may mutually agree in writing. The consummation of the Asset Purchase (the “**Closing**”) shall be conducted telephonically or via email, facsimile transfer or other similar means of correspondence and the date on which the Closing actually takes place is referred to in this Agreement as the “**Closing Date**.”

Section 3.02 Transactions to be Effected at Closing. At the Closing,

- (a) Seller shall deliver, or cause to be delivered, to Buyer an executed Bill of Sale substantially in the form attached hereto as Exhibit A;
- (b) Buyer shall deliver, or cause to be delivered, to Seller an executed Bill of Sale substantially in the form attached hereto as Exhibit A;
- (c) Seller shall deliver, or cause to be delivered, to Buyer an executed certificate from a duly authorized officer of Seller certifying as to the matters set forth in Section 6.02(c);
- (d) Buyer shall deliver, or cause to be delivered, to Seller an executed certificate from a duly authorized officer of Buyer certifying as to the matters set forth in Section 6.03(c);
- (e) Seller shall deliver, or cause to be delivered, to Buyer an executed certificate of the secretary or an assistant secretary (or equivalent duly authorized officer or other representative) of Seller certifying (i) that attached thereto are true and complete copies of all resolutions adopted by the board of directors of Seller authorizing the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby, and (ii) as to the incumbency of each person executing this Agreement and any other document delivered in connection herewith on behalf of Seller and that the signature of each such person on this Agreement and such other document is such person’s genuine signature;
- (f) Buyer shall pay or cause to be paid the Purchase Price to Seller by wire transfer of immediately available funds to an account or accounts designated in writing by Seller to Buyer in the form of Valid Account Details, such designation to occur at least five (5) Business Days prior to the Closing Date;
- (g) Seller shall deliver to Buyer: (i) a letter addressed to the FDA, substantially in the form set forth on Exhibit B hereto, and duly executed by Seller; and (ii) a letter addressed to Buyer, substantially in the form set forth on Exhibit C hereto and duly executed by Seller, acknowledging the transfer of the Priority Review Voucher from Seller to Buyer, in accordance with applicable Legal Requirements and this Agreement;

(h) Buyer shall deliver to Seller: (i) a letter addressed to the FDA, substantially in the form set forth on Exhibit B hereto, and duly executed by Buyer; and (ii) a letter addressed to Seller, substantially in the form set forth on Exhibit D hereto and duly executed by Buyer, acknowledging the transfer of the Priority Review Voucher from Seller to Buyer, in accordance with applicable Legal Requirements and this Agreement; and

(i) Seller shall deliver to Buyer a properly completed, validly executed, true and correct Internal Revenue Service Form W-9 certifying that Seller is not subject to backup withholding for United States federal income tax purposes.

Section 3.03 Title Passage. Upon the Closing, all of the right, title and interest of Seller in and to the Purchased Assets shall pass to Buyer, free and clear of all Encumbrances.

Section 3.04 Method of Delivery of Assets. Each Party shall make all notifications to the FDA as may be required under applicable Legal Requirements. Seller shall submit the FDA Notification Package to the Subject BLA through the FDA's Electronic Submission Gateway within 14 days following the Closing and within two (2) days thereafter provide Buyer with a copy of Seller's submission (the "**Seller Notice of Transfer Submission**"). Buyer shall submit the duly executed letters provided to be delivered in Section 3.02(g)(ii) and Section 3.02(h)(ii) hereof to the FDA promptly following Seller's notification to Buyer of its submission, and Buyer's receipt from Seller, of a copy of the Seller Notice of Transfer Submission, but in no event later than 30 days following the Closing (provided, that Seller timely complies with its obligations under this Section 3.04). Buyer shall promptly thereafter provide Seller with a copy of Buyer's submission. Notwithstanding the forgoing, Buyer and Seller agree to reasonably cooperate and assist each other with respect to all required or desirable filings or notifications to any Governmental Entity related to the transfer and assignment of the Purchased Assets.

ARTICLE IV. REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer, as of the Effective Date and the Closing Date (other than in respect of Section 4.05, Section 4.11 and Section 4.12, which shall only be represented and warranted as of the Closing Date), as follows:

Section 4.01 Organization, Standing and Power. Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Seller has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets, Seller's ability to consummate the transactions contemplated by this Agreement or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing. Seller is not in violation of its organizational or governing documents, as amended to date.

Section 4.02 Due Authority. Seller has all requisite corporate power and authority to enter into, perform its obligations under and consummate the transactions contemplated by this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Seller, and this Agreement has been duly executed and delivered by Seller. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Seller enforceable against Seller in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies (whether considered in an action at Law or in equity). The approval of Seller's stockholders is not required for the execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase.

Section 4.03 Non-contravention. The execution and delivery by Seller of this Agreement does not, and the consummation of the transactions contemplated hereby, including the transfer of title to, ownership in, and possession of the Purchased Assets, will not, (a) result in the creation of any Encumbrance on any of the Purchased Assets or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (i) any provision of the organizational or governing documents of Seller, in each case as amended to date, (ii) any Contract to which Seller or any of its Affiliates is a party or by which it is bound which involves or affects in any way any of the Purchased Assets or (iii) except as may be required to comply with any Legal Requirements applicable to Seller or any of the Purchased Assets.

Section 4.04 No Consents. Except for the letters referenced in Section 3.02(g) and Section 3.02(h), no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Seller to enter into, and to perform its obligations under, this Agreement.

Section 4.05 Title to Purchased Assets. As of the Closing, Seller shall represent and warrant that: Seller is the sole and exclusive owner of all rights, title and interest in and to the Purchased Assets and owns and at the Closing will transfer to Buyer good and transferable title to the Purchased Assets free and clear of any Encumbrances; Seller has performed all actions necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets pursuant to this Agreement; Seller has provided to Buyer a true, correct and complete copy of the Priority Review Voucher; and no Third Party is entitled to any portion of the proceeds of the transactions contemplated by this Agreement. As of the Closing, the right, title and interest in and to the Purchased Assets that are to be sold, transferred, conveyed, assigned and delivered by Seller to Buyer in accordance with this Agreement collectively constitutes the entire right, title and interest in and to the Purchased Assets and immediately following the Closing, Buyer shall have all right, title and interest in and to the Purchased Assets free and clear of all Encumbrances.

Section 4.06 Contracts. Except for this Agreement, there is no Contract to which Seller or any Affiliate of Seller is a party or is bound that involves or affects (or would reasonably be expected to involve or affect) the issuance, ownership, transfer, licensing, title, or use of or to any of the Purchased Assets, or that otherwise assigned, transferred, licensed, conveyed or encumbered, or granted or allowed to exist any Encumbrance with respect to, any of Seller's right, title or interest in, to or under the Purchased Assets.

Section 4.07 Compliance With Legal Requirements. Seller and its Affiliates are, and at all times have been, in material compliance with each Legal Requirement that is or was applicable to (a) Seller's and its Affiliates' conduct, acts, or omissions with respect to any of the Purchased Assets or (b) any of the Purchased Assets. Seller and its Affiliates have not received any written notice or, to Seller's Knowledge, other communication from any Person regarding any actual, alleged, possible or potential violation of, or failure to comply with, any such Legal Requirement (it being understood, for the avoidance of doubt, that any violation of, or failure to comply with, any Legal Requirement that would affect the sale, transfer or transferability of the Purchased Assets or Buyer's unencumbered use of the Purchased Assets shall be deemed "material").

Section 4.08 Legal Proceedings. There is no pending or, to Seller's Knowledge, threatened Action involving Seller or any of its Affiliates, nor has there been any Action involving Seller or any of its Affiliates, and neither Seller nor any of its Affiliates is a party or subject to the provisions of any Judgment, (a) that involves or affects (or would reasonably be expected to involve or affect) the issuance, validity,

ownership, licensing, title, or use of or to any of the Purchased Assets, including any such Action or Judgment that seeks to prohibit or limit in any respect, or place any conditions on, the ownership or use by Buyer or any of its Affiliates of any of the purchased Assets, in each case, as a result of the transactions contemplated by this Agreement, (b) that otherwise challenges or seeks to restrain, prohibit, prevent, enjoin, alter or delay the consummation of the transactions contemplated by this Agreement, or (c) that seeks to obtain from Seller, Buyer or any of their respective Affiliates in connection with the transactions contemplated by this Agreement any damages or which would result in the transactions contemplated hereby being rescinded following consummation. To Seller's Knowledge, there is no fact or circumstance that would reasonably be expected to serve as a basis for any of the foregoing Actions. None of the Purchased Assets are subject to any Order of any Governmental Entity or arbitrator.

Section 4.09 Governmental Authorizations. Neither Seller nor any of its Affiliates is required to hold any license, registration, or permit issued by any Governmental Entity to own, use or transfer the Purchased Assets, other than such licenses, registrations or permits that have already been obtained.

Section 4.10 Solvency. Seller is not entering into this Agreement with the actual intent to hinder, delay, or defraud any creditor of Seller. The remaining assets of Seller after the Closing will not be unreasonably small in relation to the business in which Seller will engage after the Closing. Upon and immediately following the Closing Date, after giving effect to all of the transactions contemplated by and in this Agreement (including the payment of the Purchase Price), Seller will not be insolvent.

Section 4.11 Revocation; Regulatory Change. As of the Closing, Seller shall represent and warrant that: (a) the Priority Review Voucher has been duly granted and has not been terminated, cancelled or revoked; (b) neither Seller nor any its Affiliates, nor to the Knowledge of Seller, any of their respective Representatives, has (i) made any untrue statement of material fact or a fraudulent statement to the FDA or any other Governmental Entity, (ii) failed to disclose a material fact or a fraudulent statement to the FDA or any other Governmental Entity or (iii) committed an act, made a statement or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Entity to invoke any similar policy; (c) to the Knowledge of Seller, there are no facts or circumstances that (with or without notice or lapse of time or both) would reasonably be expected to result in the termination, suspension, cancellation or revocation of the Priority Review Voucher or that would reasonably be expected to preclude or interfere with the sale and transfer of the Purchased Assets to Buyer or Buyer's use of the Purchased Assets following the Closing to obtain Priority Review or any other benefits associated with the Purchased Assets; (d) as exclusively relate to Seller, there are no facts or circumstances that (with or without notice or lapse of time or both) would reasonably be expected to result in the termination, suspension, cancellation or revocation of the Priority Review Voucher or that would reasonably be expected to preclude or interfere with the sale and transfer of the Purchased Assets to Buyer or Buyer's use of the Purchased Assets following the Closing to obtain Priority Review or any other benefits associated with the Purchased Assets; (e) the Priority Review Voucher was awarded to Seller by the FDA in respect of Seller's sponsorship of a rare pediatric disease product application pursuant to Section 529(b)(1) of the FDCA; (f) the Priority Review Voucher has not been transferred to any Person, including any Affiliate of Seller, and the transfer contemplated by this Agreement constitutes the first and only transfer of the Priority Review Voucher; (g) since the date that the Priority Review Voucher was issued, there has not occurred any Regulatory Change (which definition, for the purpose of this Section 4.11, shall mean any change of the kind described in clause (ii) of such definition; to Seller's Knowledge, there is no term or condition imposed by the FDA on the transferability or redemption of the Priority Review Voucher other than as set forth in the Approval Letter; and (h) Seller has provided to Buyer true, correct and complete copies of the Approval Letter (with redactions which do not relate to the Purchased Assets) and any other communications between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher or the sale thereof.

Section 4.12 Intent to Use. As of the Closing, Seller shall represent and warrant that: neither Seller nor any of its Affiliates has filed or submitted to the FDA, or instructed or permitted any Third Party to file or submit to the FDA, a Notice of Intent to Use the Priority Review Voucher to obtain a Priority Review.

Section 4.13 No Broker. Seller has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary which has been authorized to act on behalf of Seller who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 4.14 No Other Representations and Warranties. Neither Seller nor any of its Affiliates or their respective Representatives is making any representation or warranty of any kind or nature whatsoever, oral or written, express or implied, including with respect to merchantability or fitness for any particular purpose or in connection with the Purchased Assets or the accuracy or completeness of any information provided in connection with the Asset Purchase, except as otherwise expressly set forth in this Article IV and Seller and its Affiliates and their respective Representatives hereby disclaim any such other representations or warranties.

ARTICLE V. REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller, as of the Effective Date and the Closing Date, as follows:

Section 5.01 Organization, Standing and Power. Buyer is a company duly organized, validly existing and in good standing under the laws of Switzerland. Buyer has the company power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect Buyer's ability to consummate the transactions contemplated by this Agreement.

Section 5.02 Authority. Buyer has all requisite company power and authority to enter into, perform its obligations under and consummate the transactions contemplated by this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary company action on the part of Buyer, and this Agreement has been duly executed and delivered by Buyer. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Buyer enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

Section 5.03 Non-contravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the transactions contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the organizational or governing documents of Buyer, in each case as amended to date (b) any Contract to which Buyer is a party or by which it is bound which involves or affects in any way the Asset Purchase or (c) except as may be required to comply with any Legal Requirements applicable to Buyer (except, in the case of clauses (b) and (c) above, as would not, individually or in the aggregate, reasonably be expected to adversely affect the ability of Buyer to timely consummate the transactions contemplated by this Agreement).

Section 5.04 No Consents. Except for the letters referenced in Section 3.02(g) and Section 3.02(h), no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Buyer to enter into, and to perform its obligations under, this Agreement.

Section 5.05 Financing. Buyer has, and will at the Closing have, sufficient funds to consummate the transactions contemplated by this Agreement.

Section 5.06 Notice of Transfer. Buyer acknowledges that, following the Closing, it is responsible for notifying the FDA of the transfer of the Purchased Assets and the delivery to the FDA of the letters referenced in Section 3.02(g) and Section 3.02(h) in accordance with the requirements of 21 U.S.C. § 360ff(b)(2)(B) and as further described in FDA's Draft Guidance, "Rare Pediatric Disease Priority Review Vouchers – Guidance for Industry" (July 2019).

Section 5.07 No Broker. Buyer has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Buyer who would be entitled to any fee or commission payable by Seller in connection with the transactions contemplated by this Agreement.

Section 5.08 Non-Reliance. Neither Seller nor any of its Affiliates nor any of their respective Representatives makes, or has made any representation or warranty, oral or written, express or implied, as to the accuracy or completeness of any information concerning the Purchased Assets, except as expressly set forth in this Agreement, and Seller, its Affiliates and their respective Representatives expressly disclaim any and all liability that may be based on such information or errors or omissions in any such representation or warranty not expressly set forth in this Agreement, other than any liabilities arising out of or in connection with Fraud. Buyer has not relied and is not relying on any statement, representation or warranty, oral or written, express or implied (including any representation or warranty as to merchantability or fitness for a particular purpose), made by Seller, any of its Affiliates or any of their Representatives, except as expressly set forth in Article IV. Neither Seller nor its Affiliates nor any of their Representatives shall have or be subject to any liability to Buyer or any other Person resulting from the distribution to Buyer, or Buyer's use of, any information, documents or materials made available to Buyer, whether orally or in writing, in any presentations, due diligence discussions or in any other form in expectation of, or in connection with, the transactions contemplated by this Agreement, except as expressly set forth in this Agreement.

ARTICLE VI. CONDITIONS TO CLOSING

Section 6.01 Conditions Precedent of Buyer and Seller. Each Party's obligations to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent (provided, that the condition set forth at Section 6.01(a) may not be waived):

(a) Issuance of Priority Review Voucher. Seller shall have been issued the Approval Letter and granted the Priority Review Voucher by the FDA, and such Priority Review Voucher shall be free and clear of all Encumbrances. Seller shall have delivered, or have caused to be delivered, to Buyer a true, correct and complete copy of the Approval Letter (with redactions which do not relate to the Purchased Assets).

(b) No Injunctions or Restraints. No temporary restraining order, preliminary or permanent injunction or other material Order issued or promulgated by a Governmental Entity preventing, prohibiting or restraining the consummation of the transactions contemplated by this Agreement shall be in effect, and there shall not be any applicable Legal Requirement that makes consummation of the transactions contemplated by this Agreement illegal.

(c) No Governmental Litigation. There shall not be any Action commenced or pending by a Governmental Entity seeking to prohibit, limit, delay, or otherwise restrain the consummation of this Agreement and/or the transactions contemplated hereby.

Section 6.02 Buyer's Conditions Precedent. The obligations of Buyer to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Seller in this Agreement (other than the representations and warranties made by Seller in Section 4.01, Section 4.02, Section 4.03(b)(i), Section 4.05, Section 4.07, Section 4.11, Section 4.12 and Section 4.13) shall be true and correct in all respects at and as of the Effective Date and as of the Closing Date (or, if made as of a specified period or date, as of such period or date), provided, that any such failure of such representations and warranties to be true and correct shall be disregarded if it would not, individually or in the aggregate, reasonably be expected to delay, restrict, limit, preclude or otherwise negatively impact, in each case, in a material manner, the transfer and/or use of the Purchased Assets to or by Buyer. Each of the representations and warranties made by Seller in Section 4.01, Section 4.02, Section 4.03(b)(i), Section 4.07 and Section 4.13 shall be true and correct in all respects at and as of the Effective Date and the Closing Date (or, if made as of a specified period or date, as of such period or date) and each of the representations and warranties made by Seller in Section 4.05, Section 4.11 and Section 4.12 shall be true and correct in all respects at and as of the Closing Date.

(b) Performance of Covenants. All of the covenants and obligations that Seller is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Seller shall have delivered to Buyer a certificate, dated the Closing Date and duly executed by Seller, certifying that the conditions set forth in Section 6.02(a) and Section 6.02(b) have been satisfied.

(d) No Regulatory Change. There shall not have occurred and remain in effect any Regulatory Change.

(e) Deliverables. Seller shall have made the deliveries contemplated to be made by it pursuant to Section 3.02.

Section 6.03 Seller's Conditions Precedent. The obligations of Seller to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Buyer in this Agreement shall be true and correct in all material respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date), except to the extent that such representations and warranties are qualified by the term "material", or words of similar import, in which case such representations and warranties (as so written, including the terms "material", or words of similar import) shall be true and correct in all respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date).

(b) Performance of Covenants. All of the covenants and obligations that Buyer is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Buyer shall have delivered to Seller a certificate, dated the Closing Date and duly executed by Buyer, certifying that the conditions set forth in Section 6.03(a) and Section 6.03(b) have been satisfied.

(d) Deliverables. Buyer shall have made the deliveries contemplated to be made by it pursuant to Section 3.02.

ARTICLE VII. PRE-CLOSING COVENANTS AND AGREEMENTS

Section 7.01 Regulatory Change Notification. Until the earlier of the Closing or the termination of this Agreement, Seller shall, and shall cause its Affiliates to, provide Buyer: (a) true, correct and complete copies of the Approval Letter (with redactions which do not relate to the Purchased Assets), to the extent such approval is received, and any other communications between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher or the sale thereof; provided, that upon Buyer's request, Seller shall provide a true, correct and unredacted copy of the Approval Letter to Buyer's external counsel for the sole purpose of confirming that no information related to the Purchased Assets was redacted in the copy of the Approval Letter provided to Buyer; and (b) with prompt written notification of the occurrence of any Regulatory Change (which definition, for purposes of this Section 7.01, shall mean any change of the kind described in clause (ii) of such definition) of which Seller becomes aware.

Section 7.02 Commercially Reasonable Efforts. Until the earlier of the Closing, the termination of this Agreement and the receipt of the Approval Letter or a "complete response letter" (as described in 21 C.F.R. 314.110) from the FDA for the Subject BLA, Seller shall, and shall cause its Affiliates, to use commercially reasonable efforts to obtain approval of the Subject BLA, including, without limitation, making any filings to the Subject BLA requested by the FDA in accordance with applicable Legal Requirements and providing reasonable cooperation with respect to the preapproval inspection. In connection therewith, Seller shall, and shall cause its Affiliates to, (i) provide Buyer with copies of any such documents submitted to, or communication with, the FDA as reasonably requested by Buyer (with redactions of any commercially sensitive information that does not relate to the Purchased Assets) and (ii) keep Buyer reasonably apprised of the status of any communications with, and any inquiries or requests for additional information from the FDA. Notwithstanding the foregoing, and for the avoidance of doubt, nothing in this Section 7.02 shall require Seller or its Affiliates to formally appeal any decision of the FDA, bring litigation against any Person or undertake any additional clinical trials.

Section 7.03 Exclusivity; Non-Solicitation. Until the earlier of the Closing or the termination of this Agreement, Seller shall not, nor shall it authorize or instruct any of its Affiliates or its or their Representatives to, and it shall direct such Affiliates and Representatives not to, (a) sell, transfer, convey or assign the Priority Review Voucher to any Person other than Buyer or enter into any Contract with respect thereto, (b) encumber or otherwise grant or allow to exist any Encumbrance on the Priority Review Voucher (other than pursuant to this Agreement), (c) solicit, initiate or knowingly facilitate or encourage any inquiries, proposals or offers with respect to, or the submission of, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) or any inquiry, proposal or offer that is reasonably likely to lead to an Alternative Transaction, (d) engage, continue or participate in

any discussions or negotiations regarding, or take any other action intended or reasonably expected to facilitate the making of any inquiry, proposal or offer to Seller that constitutes, or may reasonably be expected to lead to, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) other than to state that they are not permitted to have any such discussions, (e) accept any inquiry, proposal or offer from any Person (other than Buyer) in respect of an Alternative Transaction, or (f) resolve to propose or agree to do any of the foregoing. Seller shall, and shall cause each of its Affiliates and shall direct its and their respective Representatives to, immediately cease and cause to be terminated any and all existing activities, discussions or negotiations, if any, with any Third Party or its Representatives conducted prior to the Effective Date with respect to any Alternative Transaction, or proposal that would reasonably be expected to lead to an Alternative Transaction, and shall use its reasonable best efforts to cause any such Third Party and its Representatives in possession of Confidential Information heretofore furnished to such Person by or on behalf of Seller to return or destroy all such Confidential Information as promptly as practicable.

ARTICLE VIII. INDEMNIFICATION

Section 8.01 Indemnification.

(a) Indemnification by Seller. From and after the Closing, Seller will indemnify, defend and hold Buyer and its Affiliates, and their respective Representatives, partners, members, successors and assigns (each, a “**Buyer Indemnitee**”) harmless for, from and against any and all Liabilities, losses, damages, claims, costs and expenses (including reasonable attorneys’ fees) (such Liabilities, losses, damages, claims, costs and expenses, together with the damages described in the provisions of Schedule 8.01(a) attached hereto, “**Damages**”), whether or not arising from, relating to or otherwise in connection with a Third Party Claim, which any Buyer Indemnitee may suffer, incur, sustain or become subject to, to the extent arising out of or resulting from (i) any breach of Seller’s representations, warranties, covenants or obligations under this Agreement or any certificate or document delivered by or on behalf of Seller hereunder, (ii) Seller’s Fraud, grossly negligent acts, omissions or misrepresentations or willful misconduct, in each case, in connection with this Agreement, (iii) any claim by any Third Party against Buyer and its Affiliates that such Third Party is entitled to any proceeds from the sale of the Priority Review Voucher pursuant hereto, and/or (iv) any Excluded Liabilities.

(b) Indemnification by Buyer. From and after the Closing, Buyer will indemnify, defend and hold Seller and its Affiliates, and their respective directors, officers, employees and agents (each, a “**Seller Indemnitee**”) harmless for, from and against any and all Damages, whether or not arising from, relating to or otherwise in connection with a Third Party Claim, which any Seller Indemnitee may suffer, incur, sustain or become subject to, to the extent arising out of or resulting from (i) any breach of Buyer’s representations, warranties, covenants or obligations under this Agreement or any certificate or document delivered by or on behalf of Buyer hereunder, (ii) Buyer’s Fraud, grossly negligent acts, omissions or misrepresentations or willful misconduct, in each case, in connection with this Agreement, and/or (iii) Buyer’s, its Affiliates’, or any subsequent transferee’s use or ownership of the Purchased Assets from and after the Closing.

Section 8.02 Indemnification Procedures for Claims.

(a) A Person entitled to indemnification pursuant to Section 8.01 will hereinafter be referred to as an “**Indemnitee**.” A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an “**Indemnitor**.”

(b) Indemnitee shall inform Indemnitor of any Third Party claim (“**Claim**”) as soon as reasonably practicable after the Claim arises, it being understood and agreed that the failure to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that such Indemnitor is actually and materially prejudiced as a result of such failure to give notice.

(c) If the Indemnitor has acknowledged in writing to the Indemnitee the Indemnitor's responsibility for defending such Claim and such Claim is not a class action or criminal matter, nor an Action seeking injunctive relief, the Indemnitor shall have the right to defend, at its sole cost and expense (with counsel reasonably selected by the Indemnitor and approved by the Indemnitee, such approval not to be unreasonably withheld or delayed), such Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnitor to a final conclusion or settled at the discretion of the Indemnitor; provided, however, that the Indemnitor may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnitee of a release from all liability in respect of such Claim; and (ii) the Indemnitee consents to such compromise or settlement, which consent shall not be unreasonably withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnitee, (B) any payment by the Indemnitee that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnitee, in which case ((A) – (C)) the Indemnitee may withhold its consent in its sole discretion. If Indemnitee determines in good faith that the defense is not being or ceases to be conducted diligently and in good faith, the Indemnitee shall have the right, at the expense of the Indemnitor, upon at least ten (10) Business Days' (or earlier if reasonably necessary to appropriately defend the Claim) prior written notice to the Indemnitor of its intent to do so, to undertake the defense of such Claim for the account of the Indemnitor (with counsel reasonably selected by the Indemnitee and approved by the Indemnitor, such approval not to be unreasonably withheld or delayed). If the Indemnitee is defending such Claim, the Indemnitee shall keep the Indemnitor apprised of all material developments with respect to such Claim and promptly provide the Indemnitor with copies of all correspondence and documents exchanged by the Indemnitee and the opposing party(ies) to such litigation. If the Indemnitor has elected to defend such Claim or if the Indemnitor has otherwise acknowledged in writing its responsibility for indemnifying a Claim, the Indemnitee may not compromise or settle such litigation without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed.

(d) The Indemnitee may participate in, but not control, any defense or settlement of any Claim controlled by the Indemnitor pursuant to this Section 8.02 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnitor shall bear such costs and expenses if counsel for the Indemnitor shall have reasonably determined that such counsel may not properly represent both the Indemnitor and the Indemnitee.

(e) A claim for indemnification for any matter not involving a Claim may be asserted by written notice to the Indemnitor. Such notice shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based and an estimate, if possible, of the amount of Damages suffered by the Indemnitee; provided, that the failure to give such notification or any deficiency in such notification will not relieve such Indemnitor from any obligations under this Article VIII, except (i) to the extent such failure to give such notification or any deficiency in such notification actually and materially prejudices such Indemnitor or (ii) as provided in Section 8.04. If the Indemnitor does not notify the Indemnitee within twenty (20) Business Days following its receipt of such notice from the Indemnitee that the Indemnitor objects to the claim received, such indemnity claim specified by the Indemnitee in such notice shall be deemed accepted by the Indemnitor, in which case, the Indemnitee may pursue its right to indemnification with respect to such indemnity claim under this Article VIII in accordance with the terms hereof.

Section 8.03 Exclusivity. From and after the Closing, other than in the event of Fraud by a Party to this Agreement on the basis of the representations and warranties contained in this Agreement, this Article VIII will provide the exclusive remedy against either Party hereto for any breach of any representation, warranty, covenant or other claim arising out of or relating to this Agreement and/or the transactions contemplated herein, except nothing in this Agreement will prevent or otherwise limit either Party from seeking or obtaining injunctive or other equitable relief for any breach of any covenant or agreement set forth herein. The Parties hereto agree that the provisions in this Agreement relating to indemnification, and the limits imposed on Buyer's remedies with respect to this Agreement and the transactions contemplated herein, were specifically bargained for between sophisticated parties and were specifically taken into account in the determination of the amounts to be paid to Seller hereunder.

Section 8.04 Limits on Indemnification. Notwithstanding anything to the contrary contained in this Agreement, the maximum aggregate amount of indemnifiable Damages that may be recovered from (a) Seller pursuant to Section 8.01(a) (other than in cases as set forth on Schedule 8.01(a)) shall equal the Purchase Price, and (b) Buyer pursuant to Section 8.01(b) shall equal the Purchase Price. Notwithstanding anything to the contrary set forth herein, except to the extent actually awarded against an Indemnitee pursuant to a judgment with respect to a Claim, no Party shall have any liability under any provision of this Agreement (including this Article VIII) for any punitive, incidental, special or indirect damages. Each Person entitled to indemnification hereunder will take commercially reasonable steps, to the extent required by applicable Legal Requirements, to mitigate all Damages after becoming aware of any event that could reasonably be expected to give rise to any Damages that are indemnifiable or recoverable hereunder or in connection herewith.

Section 8.05 Tax Treatment of Indemnity Payments. Any payments made to any Party pursuant to this Article VIII shall constitute an adjustment of the Purchase Price for Tax purposes and shall be treated as such by the Parties on their Tax Returns to the extent permitted by Legal Requirements.

Section 8.06 Buyer Knowledge. The right to indemnification pursuant to this Article VIII shall not be affected by any investigation conducted or any knowledge acquired by Buyer, its Affiliates or their respective Representatives at any time, whether before or after the execution and delivery of this Agreement or the Closing, with respect to the accuracy or inaccuracy of, or compliance with, any representation, warranty, covenant, or obligation.

ARTICLE IX. TERMINATION

Section 9.01 Termination Prior to Closing. Notwithstanding any contrary provisions of this Agreement, the respective obligations of the Parties to consummate the transactions contemplated by this Agreement may be terminated and abandoned at any time before the Closing only as follows:

(a) upon the mutual written consent of Buyer and Seller;

(b) by either Party, by written notice to the other Party if the Closing has not occurred on or before 11:59 p.m., in New York, New York, on March 31, 2024 (the "Outside Date"); provided, however, that the right to terminate this Agreement under this Section 9.01(b) shall not be available to any Party whose material breach of any provision set forth in this Agreement is the primary cause of the failure of the Closing to occur on or before such date;

(c) by Buyer, if Buyer is not in material breach of its obligations under this Agreement and there has been a violation or breach by Seller of any of its representations, warranties, covenants, or other agreements contained in this Agreement, which has prevented or would prevent the satisfaction of any condition to the Closing, and (i) such violation or breach has not been waived by Buyer, (ii) Buyer has provided written notice to Seller of such violation or breach, and (iii) such violation or breach cannot be or has not been cured by Seller within twenty (20) Business Days after receiving written notice thereof from Buyer (provided, that in no event shall such twenty (20) Business Day extend beyond the Outside Date); or

(d) by Seller, if Seller is not in material breach of its obligations under this Agreement and there has been a violation or breach by Buyer of any of its representations, warranties, covenants, or other agreements contained in this Agreement that has prevented or would prevent the satisfaction of any condition to the Closing, and (i) such violation or breach has not been waived by Seller, (ii) Seller has provided written notice to Buyer of such violation or breach, and (iii) such violation or breach cannot be or has not been cured by Buyer within twenty (20) Business Days after receiving written notice thereof from Seller (provided, that in no event shall such twenty (20) Business Day extend beyond the Outside Date).

Section 9.02 Effect of Termination.

(a) In the event of the termination of this Agreement as provided in Section 9.01, written notice thereof shall forthwith be given to the other Party specifying the provision hereof pursuant to which such termination is made, and this Agreement shall forthwith become null and void (except for the provisions of this Section 9.02, Section 10.03, Section 10.04, Section 10.05, Section 10.06, Article I and Article XI, which shall survive any such termination (together, the “**Surviving Provisions**”)) and there shall be no liability on the part of Buyer or Seller except for (i) Damages resulting from any breach of this Agreement prior to termination of this Agreement by Buyer or Seller and (ii) Damages incurred after the termination of this Agreement with respect to the Surviving Provisions.

(b) If this Agreement is terminated in accordance with (i) Section 9.01(b) and at such time, the condition set forth in Section 6.01(a) has not been satisfied, or (ii) Section 9.01(c) as a result of a material breach of Seller’s obligations related to obtaining the Priority Review Voucher, Seller shall reimburse Buyer for its out-of-pocket costs and expenses actually incurred in connection with the negotiation and execution of this Agreement), provided, that in no event shall such costs and expenses exceed One Hundred Thousand U.S. Dollars (U.S. \$100,000).

ARTICLE X. ADDITIONAL COVENANTS

Section 10.01 Further Assurances.

(a) The Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including without limitation any notifications or filings required to be made to the FDA in connection with the transfer of the Purchased Assets following the Closing, and shall (i) furnish upon request to each other such further information, (ii) execute and deliver to each other such other documents, and (iii) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the transactions contemplated by this Agreement, including the use by Buyer, its Affiliates or their respective successors and assigns of the Priority Review Voucher in accordance with its terms and applicable Legal Requirements.

(b) Without limiting the foregoing, Buyer and Seller agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment of the Purchased Assets.

Section 10.02 Compliance with Legal Requirements. Following issuance of the Approval Letter and grant to the Seller of the Priority Review Voucher, Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the rare pediatric disease product for which the Priority Review

Voucher was awarded, to at all times comply in all material respects with all Legal Requirements applicable to the Purchased Assets, including any and all Legal Requirements applicable to the validity, maintenance, use or transfer of the Priority Review Voucher, or that would reasonably be expected to result in the revocation of the Priority Review if such Legal Requirements were not complied with. Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the rare pediatric disease product for which the Priority Review Voucher was awarded, to promptly forward to Buyer any written communications or notices it or its Affiliates receives from any Governmental Entity in respect of the Purchased Assets.

Section 10.03 Nondisclosure.

(a) Subject to disclosures permitted or contemplated by Section 10.04, with respect to Confidential Information received from a Party, the other Party will (i) keep such Confidential Information confidential, (ii) not use any such Confidential Information for any reason other than to carry out the intent and purpose of this Agreement, and (iii) not disclose any such Confidential Information to any Person, except in each case as otherwise expressly permitted by this Agreement or with the prior written consent of the disclosing Party.

(b) Each Party may disclose Confidential Information of the other Party only to its Representatives on a need-to-know basis.

(c) Each Party will (i) enforce the terms of this Section 10.03 as to its Representatives, (ii) take such action to the extent necessary to cause its Representatives to comply with the terms and conditions of this Section 10.03, and (iii) be responsible and liable for any breach of this Section 10.03 by it or its Representatives.

(d) If a Party becomes compelled by a court or is requested by a Governmental Entity to make any disclosure that is prohibited or otherwise constrained by this Section 10.03, such Party shall (to the extent permitted by applicable Legal Requirements) provide the disclosing Party with prompt notice of such compulsion or request so that it may seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section 10.03. In the absence of a protective order or other remedy, the Party subject to the requirement to disclose may disclose that portion (and only that portion) of the Confidential Information that, based upon advice of its counsel, it is legally compelled to disclose or that has been requested by such Governmental Entity; provided, however, that such Party shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any Person to whom any Confidential Information is so disclosed.

(e) Nothing herein shall prohibit or otherwise restrict the disclosure of any Confidential Information by or on behalf of Buyer or its Affiliates to the FDA or other Governmental Entity to the extent required by the FDA or such other Governmental Entity to enable the use or transfer of the Priority Review Voucher; provided, that Buyer, its Affiliates and their respective Representatives shall use commercially reasonable efforts to obtain confidential treatment for any such disclosures.

Section 10.04 Disclosures Concerning this Agreement. The press release with respect to the execution of this Agreement that is attached as Exhibit E hereto shall be issued by Seller on or the next Business Day following the Effective Date. Buyer and Seller agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed), except as required by a Governmental Entity or applicable Legal Requirement (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided, that the Party intending to disclose such information shall

use reasonable efforts to provide the other Party with advance notice of such required disclosure, and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party). Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate only such information concerning this Agreement as was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement. Each Party acknowledges that the other Party, or the other Party's parent entity, as a publicly traded company is legally obligated to make timely disclosures of material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission; provided further that if a Party is obligated to so file a copy of this Agreement, such Party shall prepare a proposed redacted version thereof and request confidential treatment thereof, and the other Party may promptly provide its comments and additional proposed redactions, if any, thereon, which comments and proposed redactions, if any, shall be considered in good faith by the Party required to so file a copy of this Agreement.

Section 10.05 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity or filing that is publicly available without the prior written approval of such other Party in each instance.

Section 10.06 Expenses. Except as otherwise expressly provided herein, all costs and expenses, including, without limitation, fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the Party incurring such costs and expenses, whether or not the Closing shall have occurred.

Section 10.07 Priority Review Fee. The Priority Review Fee and all other user fees under the FDCA applicable to the human drug application for which the Priority Review Voucher is redeemed, following the Closing, shall be borne exclusively by Buyer, its Affiliates or any transferee of the Priority Review Voucher. In any event, following the Closing, Seller shall have no liability or obligation for any such fees.

Section 10.08 Marketing. Subject to approval of the Subject BLA and issuance of the Priority Review Voucher, Seller shall (or shall require any successor in interest to the rare pediatric disease product for which the Priority Review Voucher was awarded to agree to) Market in the United States the rare pediatric disease product for which the Priority Review Voucher was awarded within the 365-day period beginning on the date of the FDA approval of such rare pediatric disease product to the extent required under applicable Legal Requirements or otherwise by any applicable Governmental Entity for the continued use of, or right to transfer, the Priority Review Voucher in the United States.

ARTICLE XI. GENERAL PROVISIONS

Section 11.01 Survival. Except as expressly set forth herein, the representations and warranties and covenants which are to be performed prior to or at the Closing contained in this Agreement, and liability for the breach thereof, shall survive the Closing and shall remain in full force and effect for a period of two (2) years following the Closing Date; provided, however, that (a) the representations and warranties contained in Section 4.01, Section 4.02, Section 4.05, Section 4.12 and Section 4.13 shall survive the Closing Date and remain in full force and effect until the expiration of the applicable statute of limitations and (b) the covenants which are by their terms to be performed following the Closing shall survive the Closing and remain in full force and effect until performed in accordance with their terms.

Section 11.02 Transfer Taxes and Fees. Any and all sales, excise, use, transfer, value-added and similar Taxes assessed or incurred by reason of the sale by Seller and the purchase by Buyer of the Purchased Assets hereunder (“**Transfer Taxes**”) shall be shared equally between Seller and Buyer, regardless of which Party such Transfer Taxes are assessed against. The Party legally responsible for filing any Tax Return related to any Transfer Taxes shall timely file any such Tax Return and the other Party shall reasonably cooperate with respect to any such filings. The paying Party shall provide the other Party with evidence reasonably satisfactory to the other Party that Transfer Taxes have been paid, and the other Party shall reasonably promptly reimburse the paying Party for its share of any such Transfer Taxes. The Parties further agree, upon request, to use commercially reasonable efforts to obtain any certificate or other document from any Governmental Entity or any other Person as may be necessary to mitigate, reduce or eliminate any Transfer Tax. Notwithstanding anything to the contrary in this Agreement, the Parties acknowledge and agree that the transaction contemplated in this Agreement is a cross-border sale of rights which will not incur any sales Taxes.

Section 11.03 Notices. Any notice or other communication required or permitted to be delivered to any Party shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; (b) on the date sent by e-mail of a PDF document (with confirmation of transmission) if sent prior to 5:00 p.m. in the time zone of the intended recipient on a Business Day, and otherwise on the next Business Day or (c) upon such Party’s receipt after being sent by registered mail, by courier or express delivery service; in any case to the address set forth beneath the name of such Party below (or to such other address as such Party shall have specified in a written notice given to the other Party in accordance with this Section 11.03):

(a) if to Buyer, to:

Novartis Pharma AG
Lichtstrasse 35
CH 4056 Basel
Switzerland
Attention: General Counsel

with a copy (which shall not constitute notice) to:

Morrison & Foerster LLP
250 West 55th Street
New York
NY 10019
USA
Attention: Omar E. Pringle; Spencer D. Klein
Email: opringle@mofo.com; spencerklein@mofo.com

(b) if to Seller, to:

bluebird bio, Inc.
455 Grand Union Boulevard,
Somerville, MA 02145
Attention: Chief Executive Officer
Email: [***]

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP
10250 Constellation Blvd. Suite 1100
Los Angeles, CA 90067
Attention: Andrew Clark; Peter Handrinis
Email: Andrew.Clark@lw.com; Peter.Handrinis@lw.com

Section 11.04 Construction.

(a) The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

(b) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation” and the word “or” is not intended to be exclusive unless expressly indicated otherwise. The words “will” and “shall” have the same meaning. “Extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if.”

(c) The words “hereof,” “herein” and “hereunder” and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Except as otherwise indicated, (i) all references in this Agreement to “Articles,” “Sections,” “Schedules” or “Exhibits” are intended to refer to Articles, Sections, Schedules or Exhibits of this Agreement, and (ii) references in any Section to any clause are references to such clause of such Section.

(d) Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or).

(e) Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

(f) The captions, table of contents and headings in 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.

(g) Unless otherwise specified, (i) references to any applicable law or other Legal Requirement shall be deemed to refer to such law or Legal Requirement as amended from time to time and to any rules or regulations promulgated thereunder and (ii) references to any agreement or Contract are to that agreement or Contract as amended, modified, supplemented, extended or renewed from time to time in accordance with the terms hereof and thereof.

Section 11.05 Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that all Parties need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission (including .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

Section 11.06 Entire Agreement. This Agreement, including all exhibits and schedules attached hereto and the Confidentiality Agreement by and between the Parties dated September 28, 2023 sets forth the entire understanding of the Parties relating to the subject matter hereof and supersedes all prior agreements and understandings among or between the Parties relating to the subject matter hereof.

Section 11.07 Assignment. No Party will have the right to assign this Agreement, in whole or in part, by operation of law or otherwise, without the other Party's express prior written consent. Any attempt to assign this Agreement without such consent, will be null and void. Notwithstanding the foregoing, any Party may assign this Agreement, in whole or in part, without the consent of the other Party: (a) to a Third Party that succeeds to all or substantially all of its assets or business related to this Agreement (whether by sale, merger, operation of law or otherwise); or (b) to an Affiliate of such Party. Notwithstanding the foregoing, Buyer may assign this Agreement, in whole or in part, without Seller's consent, to any purchaser, transferee, or assignee of any of the Purchased Assets. For the avoidance of doubt, no assignment made pursuant to this Section 11.07 shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the foregoing, this Agreement will bind and inure to the benefit of each Party's successors and permitted assigns.

Section 11.08 Severability. If any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the Parties. The Parties shall use commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

Section 11.09 Remedies Cumulative.

(a) Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by law or equity upon such Party, and the exercise by a Party of any one remedy shall not preclude the exercise of any other remedy and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief.

(b) The Parties agree that irreparable harm may occur if any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise breached, and that money damages or other legal remedies may not be an adequate remedy for any such harm. Accordingly, the Parties acknowledge and hereby covenant and agree that in the event of any breach or threatened breach of the covenants, agreements, or obligations set forth in this Agreement, then in addition to any other remedy available at law or in equity, the non-breaching Party will be entitled to seek an injunction or injunctions to prevent or restrain any breaches or threatened breaches of this Agreement, and to specifically enforce the terms and provisions of this Agreement to enforce compliance with the covenants, agreements, and obligations under this Agreement. Each Party hereby covenants and agrees not to raise, and irrevocably waives, any objections to the availability of such relief that a remedy at law would be adequate and that a bond or other security will be required.

Section 11.10 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, regardless of the laws that might otherwise govern under applicable principles of conflicts of law. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United State District Court for the Southern District of New York (or if such court does not have subject matter jurisdiction, the State Court of the State of New York located in New York County) solely and specifically for the purposes of any Action or proceeding arising out of or in connection with this Agreement.

Section 11.11 WAIVER OF JURY TRIAL. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY. THIS WAIVER APPLIES TO ANY PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

Section 11.12 Amendment; Extension; Waiver. Subject to the provisions of applicable Legal Requirements, the Parties may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties. At any time, any Party may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Party, (b) waive any inaccuracies in the representations and warranties made to such Party contained herein or (c) waive compliance with any of the agreements or conditions for the benefit of such Party contained herein. Any agreement on the part of a Party to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such Party. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement.

Section 11.13 Representation By Counsel; Interpretation. Seller and Buyer each acknowledge that it has been represented by its own legal counsel in connection with this Agreement and the transactions contemplated by this Agreement. Accordingly, any rule of law, or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it, has no application and is expressly waived.

Section 11.14 No Benefit to Third Parties. Except as provided in Article VIII, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Asset Purchase Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

BUYER:
NOVARTIS PHARMA AG

By: /s/ Guillaume Vignon
Name: Guillaume Vignon

By: /s/ Mark Victor Rogers
Name: Mark Victor Rogers

SELLER:
BLUEBIRD BIO, INC.

By: /s/ Andrew Obenshain
Name: Andrew Obenshain
Title: President and Chief Executive Officer

SCHEDULE 8.01(A)
BUYER DAMAGES IN EVENT OF REVOCATION OF PRIORITY REVIEW VOUCHER

EXHIBIT A
FORM OF BILL OF SALE

EXHIBIT B
FORM OF JOINT FDA ACKNOWLEDGMENT LETTER

EXHIBIT C
SELLER'S TRANSFER ACKNOWLEDGMENT LETTER

EXHIBIT D
BUYER'S TRANSFER ACKNOWLEDGMENT LETTER

EXHIBIT E
PRESS RELEASE (SELLER)