

**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): November 29, 2022

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 November 29, 2022, bluebird bio, Inc. (the “Company”) entered into an asset purchase agreement (the “PRV Transfer Agreement”) with argenx BV (“Buyer”), pursuant to which the Company agreed to sell a Rare Pediatric Disease Priority Review Voucher (“PRV”) to Buyer. The Company was awarded the voucher under a U.S. Food and Drug Administration (“FDA”) program intended to encourage the development of certain rare pediatric disease product applications. The Company received the PRV when SKYSONA® (elivaldogene autotemcel) received accelerated approval by the FDA for the treatment of early, active cerebral adrenoleukodystrophy. Pursuant to the PRV Transfer Agreement, Buyer agreed to pay the Company \$102 million, payable in cash, upon the closing of the sale.

The PRV Transfer Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations. The transaction remains subject to customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

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 (the “Current Report”) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the completion of the transactions contemplated by the PRV Transfer Agreement. Statements using words such as “expect”, “anticipate”, “believe”, “may”, “will” and similar terms are also forward-looking statements. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 and our other filings with the Securities and Exchange Commission. Except as required by law, we undertake no obligations to make any revisions to the forward-looking statements contained in this Current Report or to update them to reflect events or circumstances occurring after the date of this Current Report, whether as a result of new information, future developments 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 November 29, 2022, by and between bluebird bio, Inc. and argenx BV.
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: November 30, 2022

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

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this “*Agreement*”) is made and entered into as of November 29, 2022 (the “*Effective Date*”), by and between Bluebird Bio, Inc., a corporation organized under the laws of Delaware (“*Seller*”), and ARGENX BV, a limited liability company organized under the laws of Belgium (“*Buyer*”). Buyer and Seller may hereinafter be referred to individually as a “*Party*” and collectively as the “*Parties*”.

RECITALS

WHEREAS, Seller is the holder of all right, title and interest in and to 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), 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) “*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%) or more 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, has other comparable ownership interest; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(b) “*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.

- (c) “**Approval Letter**” means the letter dated September 16, 2022 by the FDA approving the Subject BLA, Reference ID STN BL 125755/0.
- (d) “**Business Day**” means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in New York, New York and the Netherlands.
- (e) “**Claims**” means any claims for indemnification made by an Indemnified Party pursuant to Article VIII.
- (f) “**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 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 shall constitute Confidential Information of Buyer from and after the Closing Date.
- (g) “**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).
- (h) “**Damages**” means Liabilities, losses, damages, claims, causes of action, judgments, awards, suits, fines, penalties, costs and expenses (including reasonable attorneys’ and experts’ fees and expenses).
- (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 or transfer.
- (j) “**FDA**” means the United States Food and Drug Administration.
- (k) “**FDCA**” means the United States Federal Food, Drug, and Cosmetic Act.
- (l) “**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 or private body exercising any regulatory, taxing or other governmental or quasi-governmental authority.
- (m) “**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and the rules and regulations promulgated thereunder.

- (n) “**Indemnified Party**” means any of the Buyer Indemnified Parties or Seller Indemnified Parties, as applicable.
- (o) “**Indemnifying Party**” means any Person against whom a claim for indemnification is being asserted under any provision of Article VIII.
- (p) “**Knowledge**” means, with respect to Seller, the actual knowledge of Leslie Wilder (Head of Regulatory Science), Christopher Krawtschuk (Chief Financial Officer) and Andrew Obenshain (Chief Executive 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, 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 applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, with respect to Seller, 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 or any Contract.
- (s) “**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).
- (t) “**Order**” means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.
- (u) “**Person**” means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.
- (v) “**Priority Review**” means 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).
- (w) “**Priority Review Fee**” has the meaning set forth in Section 11.02.
- (x) “**Priority Review Voucher**” means the priority review voucher issued by the United States Secretary of Health and Human Services, Food and Drug Administration, to Seller, as evidenced in the Approval Letter, identified by priority review voucher number PRV BLA 125755/0.
- (y) “**Proceeding**” means any action, arbitration, audit, hearing, investigation, proceeding, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise **involving**, any Governmental Entity or arbitrator.

(z) “**Purchased Assets**” means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements 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 by the FDA 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 4.10 hereof) and adversely impacts the manner in which Buyer may use, receive, hold, transfer or otherwise exploit the Priority Review Voucher.

(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 125755, approved by the FDA on September 16, 2022 for SKYSONA (elivaldogene autotemcel) for slowing the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD).

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

(ee) “**Third Party Claim**” means a claim by a Third Party in respect of which payment may be sought pursuant to Section 8.01(a) or Section 8.01(b).

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, 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 other user fees required to be paid to redeem the Priority Review Voucher) (such Liabilities, “**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 Two Million Dollars (U.S. \$102,000,000.00) 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. Notwithstanding anything to the contrary in this Agreement, Buyer shall be entitled to deduct and withhold from the Purchase Price otherwise payable pursuant to this Agreement to Seller any amount required to be deducted or withheld therefrom on account of taxes under applicable Legal Requirements relating to taxes. Before making any such deduction or withholding, Buyer shall (i) 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 and (ii) cooperate with Seller to the extent reasonable in efforts by Seller to obtain such reduction of or relief from such deduction or withholding. Buyer shall timely remit to the appropriate tax authority any and all amounts so deducted or withheld and any deducted or withheld amounts shall be treated for all purposes of this Agreement as having been paid to Seller.

ARTICLE III. CLOSING

Section 3.01 Closing. The transactions set forth in Section 3.02 shall be effected on: (a) if 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 (as defined below), but subject to satisfaction or waiver of such conditions) on or prior to 11:59 PM (Eastern Time) on December 28, 2022, no later than December 30, 2022, or (b) otherwise, such date to be mutually agreed upon by Buyer and Seller, which date shall be no later than 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). 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) Seller shall deliver, or cause to be delivered, to Buyer an executed certificate from a duly authorized officer of the Seller certifying as to the matters set forth in Section 6.02(c);
- (c) Buyer shall deliver, or cause to be delivered, to Seller an executed certificate from a duly authorized officer of the Buyer certifying as to the matters set forth in Section 6.03(c);
- (d) 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;

(e) Buyer shall pay or cause the payment of (including, at Buyer's election and sole cost and expense, via a third party paying or escrow arrangement on terms mutually agreed by Buyer and Seller) 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;

(f) Seller shall deliver to Buyer a letter addressed to Buyer, substantially in the form set forth on Exhibit B hereto and duly executed by Seller, acknowledging the transfer of the Priority Review Voucher from Seller to Buyer, in accordance with this Agreement;

(g) Buyer shall deliver to Seller a letter addressed to Seller, substantially in the form set forth on Exhibit C hereto and duly executed by Buyer, acknowledging the transfer of the Priority Review Voucher from Seller to Buyer, in accordance with this Agreement; and

(h) 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.

Section 3.04 Filings; Notifications. 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, as follows:

Section 4.01 Organization, Standing and Power. Seller is a corporation duly organized and validly existing under the laws 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 or Seller's ability to consummate the transactions contemplated by this Agreement. Seller is not in violation of its certificate of incorporation or bylaws.

Section 4.02 Due Authority. Seller has the requisite corporate power and authority to enter into and perform its obligations under 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. 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 Noncontravention. 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, 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 certificate of incorporation or bylaws of Seller, (ii) any Contract to which Seller 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 the HSR Act, any Legal Requirements applicable to Seller or any of the Purchased Assets (except, in the case of clauses (ii) and (iii) above, as would not, individually or in the aggregate, have a material adverse effect on the ability of Seller to consummate the sale of the Purchased Assets at Closing and perform its other obligations under this Agreement).

Section 4.04 No Consents. Except for the letters referenced in Section 3.02(f) and Section 3.02(g) and the filing of any Premerger Notification and Report Form required under the HSR Act, 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. Seller is the sole and exclusive owner of 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 the full right to sell, transfer, convey, assign and deliver the Purchased Assets to Buyer at the Closing, 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.

Section 4.06 Contracts. Except for this Agreement, there is no Contract to which Seller or any Affiliate of Seller is a party that involves or affects the ownership of, licensing of, title to, or use of any of the Purchased Assets.

Section 4.07 Compliance With Legal Requirements. Seller and its Affiliates are, and at all times have been, in compliance in all material respects 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 the Seller's Knowledge, oral notice, or other written communication from any Person regarding any actual, alleged, possible or potential violation of, or failure to comply with, any such Legal Requirement.

Section 4.08 Legal Proceedings. There is no pending, or to Seller's Knowledge, threatened Proceeding that involves or affects (or may involve or affect) the ownership of, licensing of, title to, or use of any of the Purchased Assets. None of the Purchased Assets are subject to any Order of any Governmental Entity or arbitrator.

Section 4.09 Governmental Authorizations. Seller is not 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; Use of Purchased Assets. The Priority Review Voucher has not been redeemed, transferred, terminated, cancelled or revoked and Seller has not done or omitted to do any act (other than the actions contemplated to be taken in the future by Section 10.06), which act or omission would reasonably be expected to result in the termination, cancellation or revocation of the Priority Review Voucher. 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 and be measured from the date of the issuance of the Priority Review Voucher). Other than information set forth in FDA guidance issued in connection with the use of Priority Review Vouchers generally, Seller does not have Knowledge of any information that would preclude or interfere with Buyer's ability to use the Purchased Assets to obtain Priority Review or any other benefit associated with the Purchased Assets following the Closing. To the Knowledge of Seller, there is no term or condition imposed by the FDA on the Priority Review Voucher that is not set forth in the Approval Letter. Seller has provided to Buyer true, correct and complete copies of the Approval Letter and any other material communications between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher.

Section 4.12 [Reserved].

Section 4.13 Intent to Use. 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 4.14 No Broker. There is no 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 4.15 No Other Representations. Neither Seller nor any of its Representatives is making any representation or warranty of any kind or nature whatsoever, oral or written, express or implied, except as otherwise expressly set forth in this Article IV, and Seller hereby disclaims any such other representations and 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 close company with limited liability duly organized and validly existing under the laws of Belgium. 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. Buyer is not in violation of its organizational or governing documents, in each case as amended to date.

Section 5.02 Authority. Buyer has the requisite company power and authority to enter into and perform its obligations under 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 Noncontravention. 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, 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 the HSR Act, any Legal Requirements applicable to Buyer, except, in the case of clauses (b) and (c), as would not reasonably, individually or in the aggregate, 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(d) and Section 3.02(e) and the filing of any Premerger Notification and Report Form required under the HSR Act, 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 Closing have, sufficient funds to consummate the transactions contemplated by this Agreement.

Section 5.06 Notice of Transfer. Buyer acknowledges that 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(f) and Section 3.02(g) 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 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 contained herein or made available in connection with Buyer's investigation of the foregoing, except as expressly set forth in this Agreement, and Seller, its Affiliates and their Representatives expressly disclaim any and all liability that may be based on such information or errors therein or omissions therefrom. 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 Asset Purchase, other than 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:

(a) HSR Act. The applicable waiting period under the HSR Act relating to the transactions contemplated by this Agreement shall have expired or been terminated.

(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 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 Proceeding 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 4.05, Section 4.08, Section 4.11, Section 4.13, and Section 4.14) 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), *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 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 4.05, Section 4.08, Section 4.11 Section 4.13, and Section 4.14 shall be true and correct in all respects at and as of the Closing Date (or, in each case, 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 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.

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.

ARTICLE VII. PRE-CLOSING COVENANTS AND AGREEMENTS

Section 7.01 Antitrust Notification.

(a) The Parties shall use their commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary or desirable under applicable Legal Requirements to consummate the transactions contemplated by this Agreement. The Parties acknowledge that, on November 28, 2022, Seller and Buyer filed, or caused their ultimate parent entities as defined in the HSR Act to file, the notifications required under the HSR Act, and the Parties shall respond as promptly as practicable to all inquiries or requests received from the Federal Trade Commission, the Antitrust Division of the U.S. Department of Justice or any other Governmental Entity for additional information or documentation. In connection therewith, the Parties shall, or shall cause their respective Affiliates to, (i) furnish to the other Party such necessary information and reasonable assistance as the other Party may reasonably request in connection with its preparation of any filing or submission that is necessary under the HSR Act, and (ii) keep the other Party reasonably apprised of the status of any communications with, and any inquiries or requests for additional information from the applicable Governmental Entity. If made available by the relevant Governmental Entity, the Parties shall request early termination of the waiting period under the HSR Act.

(b) Subject to applicable confidentiality restrictions or restrictions required by applicable Legal Requirements, each Party will notify the other promptly upon the receipt of (a) any comments or questions from any Governmental Entity in connection with any filings made pursuant to Section 7.01 or the transactions contemplated by this Agreement and (b) any request by any Governmental Entity for information or documents relating to an investigation of the transactions contemplated by this Agreement. Without limiting the generality of the foregoing, each Party shall provide to the other (or the other's respective advisors) upon request copies of all correspondence between such Party and any Governmental Entity relating to the transactions contemplated by this Agreement. The Parties may, as they deem advisable and necessary, designate any competitively sensitive materials provided to the other under this Section 7.01 as "outside counsel only." Such materials and the information contained therein shall be given only to outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient without the

advance written consent of the Party providing such materials. In addition, to the extent reasonably practicable, all discussions, telephone calls, and meetings with a Governmental Entity regarding the transactions contemplated by this Agreement shall include representatives of both Parties. Subject to applicable Legal Requirements, the Parties will consult and cooperate with each other in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, and proposals made or submitted to any Governmental Entity regarding the transactions contemplated by this Agreement by or on behalf of any Party.

(c) Notwithstanding the foregoing, nothing in this Agreement shall require, or be construed to require, the Parties or any of their respective Affiliates to offer or agree to (a) (i) sell, hold, hold separate, divest, license, discontinue or limit, before or after the Closing Date, any assets, businesses, equity holdings, intellectual property, or other interests or (ii) any conditions relating to, or changes or restrictions in, the operations of any such assets, businesses, equity holdings, intellectual property or interests (including but not limited to any requirements to enter into new Contracts or modify or terminate existing Contracts) or (b) any material modification or waiver of the terms and conditions of this Agreement.

(d) Buyer shall bear all filing fees related to any notifications under the HSR Act.

Section 7.02 Regulatory Change Notification. Until the earlier of the Closing or the termination of this Agreement, Seller shall provide Buyer with prompt written notification of the occurrence of any Regulatory Change (which definition, for purposes of this Section 7.02, shall mean any change of the kind described in clause (ii) of such definition) of which Seller becomes aware.

Section 7.03 Exclusivity; Non-Solicitation. Until the earlier of the Closing or the termination of this Agreement, Seller shall not (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), (d) engage, continue or participate in any discussions or negotiations regarding 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; provided, that, notwithstanding the foregoing, the Seller shall be entitled to engage, continue or participate in discussions and negotiations regarding a potential financing arrangement secured on, among other assets, the Purchased Assets and may, solely to the extent such potential financing involving the Purchased Assets would only be consummated following the termination of this Agreement in accordance with its terms, accept proposals or enter into agreements with respect to such potential financing.

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 (each, a "**Buyer Indemnified Party**") harmless for, from and against any and all Damages which any Buyer Indemnified Party may suffer, incur, sustain or become subject to, arising out of or resulting from (i) any breach or violation of or inaccuracy in any representations or warranties of Seller under this Agreement, (ii) any breach or violation of any covenant or agreement of Seller under this Agreement, (iii) Seller's grossly negligent acts, omissions or misrepresentations or willful misconduct, in each case, in connection with this Agreement 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 Representatives (each a “*Seller Indemnified Party*”) harmless for, from and against any and all Damages which any Seller Indemnified Party may suffer, incur, sustain or become subject to, arising out of or resulting from (i) any breach or violation of or inaccuracy in any representations or warranties of Buyer under this Agreement, (ii) any breach or violation of any covenant or agreement of Buyer under this Agreement, (iii) Buyer’s grossly negligent acts, omissions or misrepresentations or willful misconduct, in each case, in connection with this Agreement or (iv) Buyer’s, its Affiliates’ or any subsequent transferee’s use or ownership of the Purchased Assets.

Section 8.02 Notice of Loss; Third Party Claims.

(a) A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice to the Party from whom indemnification is sought. 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 or reasonably expected to be suffered by the Indemnified Party.

(b) In the event that any claim shall be instituted or asserted by any third party in respect of which payment may be sought under Section 8.1(a) or Section 8.1(b) hereof, the Indemnified Party shall promptly cause written notice of the assertion of any Third Party Claim of which it has knowledge which is covered by the provisions of Section 8.1(a) or Section 8.1(b), as applicable, to be forwarded to the Indemnifying Party. The failure of the Indemnified Party to give reasonably prompt notice of any Third Party Claim shall not release, waive or otherwise affect the Indemnifying Party’s obligations with respect thereto except to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party shall have the right, at its sole option and expense, to be represented by counsel reasonably acceptable to the Indemnified Party and to defend against, negotiate, settle or otherwise deal with any Third Party Claim which relates to any Damages indemnified by it hereunder, subject to the provisions below; provided, however, that the Indemnifying Party may not assume control of defense to a Third Party Claim (i) in which equitable relief other than monetary damages is sought, or (ii) if the Indemnifying Party has not notified the Indemnified Party in writing that, based on the facts and circumstances known at such time, the Indemnified Party may be liable to indemnify the Indemnified Party with respect to the Damages relating to such Third Party Claim subject to the terms of this Article VIII. If the Indemnifying Party elects to defend against, negotiate, settle or otherwise deal with any Third Party Claim which relates to any Damages indemnified by it hereunder, it shall within thirty (30) days (or sooner, if the nature of the Third Party Claim so requires) notify the Indemnified Party of its intent to do so. If the Indemnifying Party elects not to defend against, negotiate, settle or otherwise deal with any Third Party Claim which relates to any Damages indemnified against hereunder, or is not permitted to assume the defense of a Third Party Claim pursuant to the proviso to the third sentence of this Section 8.2(b), the Indemnified Party may defend against, negotiate, settle or otherwise deal with such Third Party Claim, subject to the provisions below. If the Indemnifying Party shall assume the defense of any Third Party Claim pursuant to the terms of this Agreement, the Indemnified Party may participate, at his or its own expense, in the defense of such Third Party Claim; provided, however, that such Indemnified Party shall be entitled to participate in any such defense with separate counsel (the expense of which may constitute Damages hereunder subject to the terms of this Article VIII) if (A) so requested by the Indemnifying Party to participate or (B) in the reasonable opinion of outside counsel to the Indemnified Party a conflict or potential conflict exists between the Indemnified Party and the Indemnifying Party that would make such separate representation advisable. The Parties hereto agree to reasonably cooperate with each other in connection with the defense, negotiation or settlement of any such Third Party Claim. Notwithstanding

anything in this Section 8.2 to the contrary, neither an Indemnified Party nor an Indemnifying Party shall, without the written consent of the other, settle or compromise any Third Party Claim or permit a default or consent to entry of any judgment unless (1) the claimant provides to the Indemnified Party and the Indemnifying Party an unqualified release from all liability in respect of such Third Party Claim, (2) such settlement does not involve any injunctive relief binding upon the Indemnified Party or any of its Affiliates, (3) such settlement does not encumber any of the material assets of any Indemnified Party or impose any restriction or condition that would apply to or materially affect any Indemnified Party or the conduct of any Indemnified Party's business, and (4) such settlement does not involve any admission of liability or wrongdoing by any Indemnified Party, Indemnifying Party or any of its Affiliates.

Section 8.03 Adjustments. Any amount paid under this Article VIII shall be treated as an adjustment to the Purchase Price for all tax purposes unless otherwise required by applicable Legal Requirements.

Section 8.04 Limitations 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) 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 Indemnified Party 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 or damages for or otherwise based on business interruption, diminution of value, loss of future revenue, profits or income, or loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement. Each Person entitled to indemnification hereunder will take commercially reasonable steps 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 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 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.

Section 8.06 Exclusive Remedy. From and after the Closing, except in the case of fraud, the sole and exclusive remedy of any Indemnified Party for any Damages that such Indemnified Party may at any time suffer or incur, or become subject to, as a result of, or in connection with this Agreement, including any inaccuracy, violation or breach of any representation and warranty contained in this Agreement by any Party, or any failure by any Party to perform or comply with any covenant or agreement that, by its terms, was to have been performed, or complied with, under this Agreement, shall be indemnification in accordance with this Article VIII (subject to the applicable qualifications and limitations set forth in this Agreement).

ARTICLE IX. TERMINATION

Section 9.01 Termination Prior to Closing. Notwithstanding any contrary provisions of this Agreement, this Agreement and 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., Cambridge Massachusetts time, on January 31, 2023; *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; or

(c) by Seller, by written notice to Buyer, if (i) the Closing has not occurred on or before 5:59 p.m. Cambridge Massachusetts time, on December 30, 2022, (ii) at such time the conditions to Closing in Section 6.01 and Section 6.02 other than those required to be satisfied by Buyer have been satisfied or waived by Buyer as of such time, and (iii) Seller has, prior to such time, delivered to Buyer or its representatives, subject only to the occurrence of the Closing, the documentation required to be delivered by Seller pursuant to Section 3.02; *provided, however*, that Seller may not exercise this right solely as a result of Seller not having received the Purchase Price prior to 5:59 p.m. Cambridge Massachusetts time in circumstances where the Buyer has irrevocably actioned the payment of the Purchase Price to the account with the Valid Account Details (and provides written evidence (including for such purposes via e-mail or PDF) of such irrevocable payment instructions to Seller) on or before such time.

Section 9.02 Effect of Termination. 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, Article I and Article XI, which shall survive any such termination) and there shall be no liability on the part of Buyer or Seller except for damages resulting from any breach of this Agreement prior to termination of this Agreement by Buyer or Seller.

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, 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. 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 use or transfer 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, promptly forward to Buyer any communications or notices it or its Affiliates receive from

any Governmental Entity in respect of the Purchased Assets. Without limiting the generality of the immediately preceding sentence, to the extent required, now or in the future, under applicable Legal Requirements or otherwise by FDA for the use or transfer of the Priority Review Voucher, or to avoid revocation of the Priority Review Voucher, Seller shall, and shall cause its Affiliates and its and their respective successors in interest to the rare pediatric disease product for which the Priority Review Voucher was awarded to, submit a post-approval production report to the United States Secretary of Health and Human Services not later than five (5) years after the approval of such rare pediatric disease product in accordance with 21 U.S.C. § 360ff(e)(2).

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 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.

Section 10.04 Disclosures Concerning this Agreement. The press release with respect to the execution of this Agreement that is attached as: (a) Exhibit D-1 hereto shall be issued by Seller, and (b) Exhibit D-2 hereto shall be issued by Buyer, in each case, on 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 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 Expenses. Whether or not the Asset Purchase and the other transactions contemplated by this Agreement are consummated, and except as otherwise expressly set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred or owed in connection with the purchase and sale of the Purchased Assets, this Agreement and the transactions contemplated hereby.

Section 10.06 Marketing. 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 4.08, Section 4.11, Section 4.13 and Section 4.14, 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, value-added and similar taxes, fees or duties assessed or incurred by reason of the sale by Seller and the purchase by Buyer of the Purchased Assets hereunder shall be borne equally by Buyer and Seller, regardless of which Party such taxes, fees or duties are assessed against. Buyer, its Affiliates, or any Buyer transferee of the Priority Review Voucher shall be solely responsible for the payment of the priority review fee described in 21 U.S.C. § 360ff(c) (the "**Priority Review Fee**") and all other user fees applicable to the human drug application for which the Priority Review Voucher is redeemed, following the Closing. For the avoidance of doubt, following the Closing, Seller shall have no liability or obligation for any such fees.

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; (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:
argenx BV
Industrial Zwijnaarde 7
9052 Zwijnaarde (Ghent)
Belgium
Attention: [***]
Email: [***]

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

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Michael H. Bison
Email: MBison@goodwinlaw.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, regulations or interpretations 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 or facsimile 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 November 26, 2022, 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. 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.

Section 11.10 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts, 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 state and federal courts in the Commonwealth of Massachusetts solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

Section 11.11 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 11.12 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.

[SIGNATURE PAGE FOLLOWS]

SELLER:

bluebird bio, Inc.

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

BUYER:

ARGENX BV

By: /s/ Tim van Hauwermeiren
Name: Tim van Hauwermeiren
Title: CEO

EXHIBIT A
FORM OF BILL OF SALE

EXHIBIT B
SELLER'S TRANSFER ACKNOWLEDGMENT LETTER

EXHIBIT C
BUYER'S TRANSFER ACKNOWLEDGMENT LETTER

EXHIBIT D-1
PRESS RELEASE (SELLER)

EXHIBIT D-2
PRESS RELEASE (BUYER)