

**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): March 6, 2020

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 No.)

**60 Binney Street,
Cambridge, MA**

(Address of Principal Executive Offices)

02142

(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 (see General Instructions A.2. below):

- 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 March 6, 2020, bluebird bio (Switzerland) GmbH, a wholly-owned subsidiary of bluebird bio, Inc. (“bluebird”) and Apceth Biopharma GmbH entered into an amendment (the “Amendment”) to the Toll Manufacturing and Service Agreement, effective January 1, 2017, for the manufacture of the drug product (the “Agreement”) to modify the terms applicable to reserved production capacity.

The foregoing description of the terms of the Amendment does not purport to be complete, and is qualified in its entirety by reference to the full text of the Amendment, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	† Amendment Agreement No. 3 to the Toll Manufacturing and Service Agreement by and between bluebird bio (Switzerland) GmbH and Apceth Biopharma GmbH
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Certain portions of the exhibit (indicated by asterisks) have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is (i) not material and (ii) would likely cause competitive harm to bluebird if publicly disclosed.

**Amendment Agreement No. 3
to the
Toll Manufacturing and Service Agreement**

Amendment Agreement No. 3 ("**Amendment No. 3**") to the Toll Manufacturing and Service Agreement (i.e. the TMSA as further defined below) shall become effective from the date on which it was signed by the last Party and is entered into by and between:

bluebird bio (Switzerland) GmbH ("BBB")

having its principal place of business at Dammstraße 21, 6300 Zug, Switzerland,

and

Apceth Biopharma GmbH ("APCETH")

having its principal place of business at Haidgraben 5, 85521 Ottobrunn, Germany

BBB and APCETH hereinafter also each referred to as a "**Party**" and jointly as the "**Parties**".

Furthermore,

bluebird bio Inc.

having its principal place of business at 60 Binney St., Cambridge, MA 02142, United States of America,

acknowledges this Amendment No. 3 as guarantor for BBB's obligations under the TMSA.

Whereas,

bluebird bio, Inc., APCETH and KG entered into a Toll Manufacturing and Service Agreement effective on January 1, 2017 regarding the clinical and commercial GMP-manufacturing of bluebird bio, Inc.'s Products and related services by APCETH, including an Addendum of May 21, 2018 regarding the European Union's General Data Protection Regulation and an Amendment No. 1 of November 16, 2018 regarding indemnification of APCETH (collectively the "**TMSA**"). By letter of May 15, 2019, received by APCETH at May 22, 2019, bluebird bio, Inc. formally assigned and transferred the TMSA to its subsidiary BBB (the "**Assignment**") in accordance with the provisions of Section 23.1 of the TMSA effective April 28, 2019 as further reflected in Amendment Agreement No. 2 to the TMSA effective September 5, 2019.

The Parties now wish to make further amendments to the TMSA as detailed herein in this Amendment No. 3.

NOW THEREFORE, the Parties agree as follow:

1. Amendments to the TMSA

1.1 Section 1.12 of the TMSA shall be replaced by the following revised Section 1.12:

1.12 "**Clean Room**" shall mean [***].

1.2. Section 1.34 of the TMSA shall be replaced by the following revised Section 1.34:

1.34 "**Product**" shall mean the autologous cells transduced with a defined lentiviral vector suspended in cryopreservative solution in the final immediate container for [***].

1.3 In Section 3.2 of the TMSA, new subsections (c) and (d) shall be added as follows:

(c) **Availability of a [***]**. At any time after the effective date of Amendment No. 3 to this Agreement, BBB shall [***].

(d) **Additional [***]**. If the Parties come to the conclusion [***].

1.4 Section 4.2 of the TMSA, including its subsections (a) through (f), shall be replaced by the following revised Section 4.2; the new Schedule 4 introduced thereby is attached hereto as Annex 3:

4.2 Capacity, Production Scenarios, Forecasts, Additional Batch and Cancellation Fee. The reserved production capacity of the Clean Rooms and the minimum and maximum amount of Batches to be ordered by BBB and to be delivered by APCETH for each [***] is determined by the Production Scenarios set forth in ascending order in Section 1 of Schedule 4 elected by BBB (each a “**Production Scenario**”) and as further provided and subject to Schedule 4.

1.5 Behind current Section 4.3 of the TMSA a new Section 4.4 shall be added:

4.4 Multi-Batch Processing / Staggered Start. For the avoidance of doubt, each Batch as defined in Section 1.7 of this TMSA is a quantity of a Product [***].

1.6 Behind new Section 4.4 of the TMSA a new Section 4.5 shall be added:

4.5 Product Overlaps. BBB acknowledges that currently APCETH may only manufacture one kind of Product [***].

1.7 Section 5.3 of the TMSA shall be deleted.

1.8 Behind new Section 5.5 of the TMSA the following new Section 5.6 shall be added to the TMSA:

5.6 Undelivered Product. APCETH shall inform BBB in writing [***].

1.9 In Section 6.1 of the TMSA, the following sentence shall be added to the existing provision after the first sentence and before the current second and third (then third and fourth) sentences; ‘Schedule 5’ referred to in such new sentence is attached to this Amendment No. 3 as Annex 1.9:

BBB shall target to maintain and timely provide to APCETH sufficient stock level—either in on-site or third-party storage—of Supplied Materials as necessary to enable APCETH to manufacture the amount of Batches forecasted for approximately [***] under the then current Forecast; as defined in more detail in Schedule 5 (“**Critical BBB Supplied Raw Material**”). If supply of BBB sourced material becomes a constraint, BBB will communicate and work with APCETH to manage supplies in an appropriate manner.

1.10 Behind the current Section 6.3 of the TMSA, new Sections 6.4, and 6.5 to the TMSA shall be added; ‘Schedule 6’ referred to in such new Section 6.4 is attached to this Amendment No. 3 as Annex 1.9:

6.4 Apceth shall target to maintain a sufficient stock level of material essential for the manufacture of the Product other than the Supplied Material as necessary to manufacture the amount of Batches forecasted under the then current Forecast for the following [***]; as defined in more detail in Schedule 6 (“**Critical Apceth Supplied Raw Material**”). On hand BBB-supplied critical raw materials and hand inventory of Drug Product will be reported to BBB [***]. If supply of APCETH-sourced material becomes a constraint,

APCETH will communicate and work with BBB to manage supplies in an appropriate manner.

6.5 Apceth, acting in its own name and on behalf of BBB as an indirect representative of BBB for customs purposes, will make all customs declarations to the competent authorities for the import (release for free circulation in the EU) of the Supplied Material by BBB under this Agreement. Therefore, BBB ensures that it will to best of its knowledge provide Apceth all necessary, correct and complete information, including the declared value, required for the import of the Supplied Materials.

1.11 In Section 11.1 of the TMSA, a new subsection (c) shall be added as follows:

(c) [***]: One million (1,000,000) EUR.

1.12 Section 11.2 of the TMSA shall be replaced by the following revised Section 11.2:

11.2 Maintenance Fee. Effective following the Supply Initiation Date, BBB shall pay to APCETH a maintenance fee to [***]. The Maintenance Fee for the [***]. Effective following the Extension Date, the [***] to be paid by BBB to APCETH shall amount to [***]; provided, however, that

(i) the applicable Maintenance Fee for the calendar year [***]; and

(ii) prior to BBB's exclusive access to [***].

1.13 Section 11.3 of the TMSA shall be replaced by the following revised Section 11.3:

11.3 Production Fees.

(a) The Production Fee for each Production Year shall represent the [***]. For any Additional Batch, to the extent that a Production Scenario allows for Additional Batches, the price per Additional Batch set forth in Section 3 of Schedule 4 ("**Additional Batch Price**") shall apply.

(b) The respective (minimum) Production Fee shall be due and payable in [***], where the Production Fee applicable to [***]. Any Additional Batch Prices will be invoiced [***].

1.14 Section 11.8 of the TMSA shall be replaced by the following revised Section 11.8:

11.8 Invoice. APCETH will invoice BBB [***].

1.15 Section 16.2 of the TMSA, as last changed by Amendment No. 1 thereto, shall be replaced with the following Section 16.2:

16.2 Indemnification of APCETH. BBB will indemnify APCETH, its Affiliates, its approved subcontractors and its and their respective directors, officers, employees, independent contractors, consultants and agents (the "APCETH Parties"), and defend and hold each of them harmless, from and against any and all Losses to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of: [***].

1.16 Schedule 1 of the TMSA shall be replaced by the updated Schedule 1 attached hereto.

1.17 Schedule 2 shall be replaced by the updated Schedule 2 attached hereto.

1.18 Schedule 3 shall be replaced by the updated Schedule 3 attached hereto.

1.19 Except as expressly provided in Sections 1.1 through 1.18 of this Amendment No. 3, all other terms, conditions and provisions of the TMSA shall continue in full force and effect as provided therein.

2. Severability

If any provision of this Amendment No. 3 is or becomes invalid, either as a whole or in part, this shall not affect the validity or enforceability of the remainder of this Amendment No. 3 or the Agreement. The Parties agree to replace the invalid provision by a provision which serves the purposes of this Amendment No. 3 and the Agreement as closely as possible. The same shall apply to any possible omission in this Amendment No. 3. If the defectiveness of a provision is based on the determination of a certain level of performance or a certain time (deadline or fixed date), the provision is deemed to have been agreed with the level or time which comes as close as legally possible to the original level or time.

(Signature page follows)

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the Parties have caused this Amendment No. 3 to be executed and delivered by their respective duly authorized officers

bluebird bio (Switzerland) GmbH **apceth Biopharma GmbH**

Zug, 06-Mar-2020 Ottobrunn 05.03.2020
(Place, Date) (Place, Date)

/s/ David Seeberger /s/ Dusan Kosijer
Name: David Seeberger Name: Dusan Kosijer
Title: Head of Finance, Europe Title: CFO

Acknowledged as guarantor according
to Section 23.1 TMSA:

bluebird bio, Inc.

Cambridge, MA 06-Mar 2020
(Place, Date)

/s/ Jason Cole
Name: Jason Cole
Title: Chief Operating and Legal Officer

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]

apceth ./ . BBB
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