
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 8-K

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

Date of Report (Date of earliest event reported): October 15, 2021

WAVE LIFE SCIENCES LTD.

(Exact name of registrant as specified in its charter)

Singapore
(State or other jurisdiction
of incorporation)

001-37627
(Commission
File Number)

00-000000
(IRS Employer
Identification No.)

7 Straits View #12-00, Marina One
East Tower
Singapore
(Address of principal executive offices)

018936
(Zip Code)

Registrant's telephone number, including area code: +65 6236 3388

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 Instruction 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))

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.

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

| Title of each class | Trading symbol | Name of each exchange on which registered |
|--------------------------------------|-------------------|--|
| \$0 Par Value Ordinary Shares | WVE | The Nasdaq Global Market |

Item 1.01 Entry Into a Material Definitive Agreement.*Amendment to Collaboration and License Agreement with Takeda*

On October 15, 2021, Wave Life Sciences USA, Inc. and Wave Life Sciences UK Limited, each direct, wholly owned subsidiaries of Wave Life Sciences Ltd. (collectively, “Wave” or the “Company”) and Takeda Pharmaceutical Company Limited (“Takeda”) entered into the Second Amendment (the “Amendment”) to the Collaboration and License Agreement dated February 19, 2018 (the “Collaboration Agreement”), which amended the Category 2 component of the two-part collaboration. As previously disclosed, under Category 2 of the Collaboration Agreement, Wave had granted Takeda the right to exclusively license multiple preclinical programs for central nervous system (CNS) disorders during a four-year research term. Pursuant to the terms of the Amendment, effective as of October 15, 2021, Wave and Takeda discontinued the Category 2 component of the Collaboration Agreement and Takeda will pay Wave an additional \$22.5 million for collaboration-related research and preclinical expenses. As a result of the Amendment, Wave is free to advance its CNS programs independently or enter partnerships in the CNS field outside of the three specified targets (listed below) that are part of the ongoing late-stage Category 1 component of the collaboration between the companies.

The Category 1 component of the original Collaboration Agreement remains in effect and is unchanged by the Amendment. The Category 1 component pertains to Takeda’s option to co-develop and co-commercialize Wave’s investigational CNS therapies for three targets: C9orf72, HTT and ATXN3, including WVE-004 and WVE-003. WVE-004 and WVE-003 are currently being investigated in the ongoing Phase 1b/2a FOCUS-C9 clinical trial for the treatment of amyotrophic lateral sclerosis and frontotemporal dementia, and the ongoing Phase 1b/2a SELECT-HD clinical trial for the treatment of Huntington’s disease, respectively. Should Takeda opt in on any of these programs, Wave would receive an opt-in payment and would lead manufacturing and joint clinical co-development activities. Takeda would lead joint co-commercial activities in the United States and all commercial activities outside of the United States. Global costs and potential profits would be shared 50:50 and Wave would be eligible to receive development and commercial milestone payments.

The foregoing description of the material terms of the Amendment is qualified in its entirety by reference to the complete text of the Amendment, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission as an exhibit to the Company’s Annual Report on Form 10-K for the fourth quarter and fiscal year ended December 31, 2021.

Item 7.01 Regulation FD Disclosure.

On October 18, 2021, the Company issued a press release announcing the Amendment. A copy of this press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

The information in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 7.01 is furnished and not filed:

| Exhibit No. | Document |
|--------------------|--|
| 99.1 | Press Release issued by Wave Life Sciences Ltd. dated October 18, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

SIGNATURES

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

WAVE LIFE SCIENCES LTD.

By: /s/ Paul B. Bolno, M.D.

Paul B. Bolno, M.D.

President and Chief Executive Officer

Date: October 18, 2021



Wave Life Sciences and Takeda Amend CNS Collaboration

Amendment to ongoing collaboration allows Wave to advance or partner CNS programs, including those using ADAR editing

Takeda option to co-develop and co-commercialize late-stage CNS programs, including clinical programs WVE-004 and WVE-003, remains unchanged

CAMBRIDGE, Mass., October 18, 2021 – Wave Life Sciences Ltd. (Nasdaq: WVE), a clinical-stage genetic medicines company committed to delivering life-changing treatments for people battling devastating diseases, today announced an amendment to its ongoing collaboration with Takeda Pharmaceutical Company Limited, which immediately discontinues the discovery research component of the collaboration that provided Takeda with the right to license multiple preclinical programs for central nervous system (CNS) indications over a four-year research term. Under terms of the amendment, Takeda will pay Wave \$22.5 million for collaboration-related research and preclinical expenses. The amendment announced today allows Wave to advance CNS programs independently or enter partnerships in the CNS field outside of the three specified targets, which are part of the ongoing late-stage collaboration between the companies.

The late-stage component of the original collaboration led by Wave remains unchanged, including Takeda’s option to co-develop and co-commercialize CNS therapies for three targets, C9orf72, HTT and ATXN3, including WVE-004 and WVE-003. WVE-004 and WVE-003 are currently being investigated in the ongoing Phase 1b/2a FOCUS-C9 clinical trial for the treatment of amyotrophic lateral sclerosis and frontotemporal dementia, and the ongoing Phase 1b/2a SELECT-HD clinical trial for the treatment of Huntington’s disease, respectively. Should Takeda opt in on any of these programs, Wave would receive an opt-in payment and would lead manufacturing and joint clinical co-development activities. Takeda would lead joint co-commercial activities in the United States and all commercial activities outside of the United States. Global costs and potential profits would be shared 50:50 and Wave would be eligible to receive development and commercial milestone payments.

“This amendment streamlines our existing collaboration with Takeda and immediately enables us to advance or partner early-stage CNS programs, outside of the C9orf72, HTT, and ATXN3 targets, and including those leveraging our ADAR editing capability,” said Paul Bolno, MD, MBA, President and Chief Executive Officer of Wave Life Sciences. “Over many years, the collaboration with Takeda has yielded value for Wave and the patients we aim to serve. We look forward to continuing the partnership as we advance our ongoing clinical programs.”

Wave’s cash runway remains unchanged. The company expects that its existing cash and cash equivalents, together with expected and committed cash from its existing collaboration, will enable the company to fund its operating and capital expenditure requirements into the second quarter of 2023.

About Wave Life Sciences

Wave Life Sciences (Nasdaq: WVE) is a clinical-stage genetic medicines company committed to delivering life-changing treatments for people battling devastating diseases. Wave aspires to develop best-in-class medicines across multiple therapeutic modalities using PRISM, the company’s proprietary discovery and drug development platform that enables the precise design, optimization and production of stereopure oligonucleotides. Driven by a resolute sense of urgency, the Wave team is targeting a broad range of genetically defined diseases so that patients and families may realize a brighter future. To find out more, please visit www.wavelifesciences.com and follow Wave on Twitter @WaveLifeSci.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the collaboration and license agreement between Wave and Takeda, including the current amendment and the terms and payment related thereto; the anticipated benefits of the amendment; and the anticipated duration of our cash runway. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release and actual results may differ materially from those indicated by these forward-looking statements as a result of these risks, uncertainties and important factors, including, without limitation, the risks and uncertainties described in the section entitled “Risk Factors” in Wave’s most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), as amended, and in other filings Wave makes with the SEC from time to time. Wave undertakes no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

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