Ascelia Pharma

Complete Response Letter for Orviglance NDA

- Additional clinical data and product documentation requested
- Urgent FDA meeting to discuss next steps
- Very low visibility: Valuation suspended until more clarity

Additional clinical data and product documentation requested

Ascelia Pharma announced today that it has received a Complete Response Letter (CRL) from the FDA regarding the NDA for Orviglance. The FDA has stated that it cannot approve the application in its present form and has requested additional clinical data and product documentation. It remains unclear at this stage whether the FDA's request amounts to a relatively modest data addition, which could potentially result in a delay of only around six months, or whether a new pivotal clinical trial will be required. The latter would represent a significantly longer and more costly development path and raises serious questions about its financial and operational feasibility. The company has confirmed a cash runway into 2027 and will assess potential cost-saving initiatives.

Urgent FDA meeting to discuss next steps

Ascelia intends to request a Type A meeting with the FDA as soon as possible to clarify the requirements and discuss a path forward. Given the urgency associated with Type A meetings, the FDA aims to respond to such requests within 14 days and, if granted, schedule the meeting within 30 days. The FDA's negative response came as a surprise given that the pivotal Phase 3 trial successfully met its primary endpoint, demonstrating that the company's MRI contrast agent Orviglance significantly ($p < 0.001$) improved the visualisation of metastatic liver lesions compared with un-enhanced MRI, with the secondary endpoints further supporting these results. Reflecting this surprise, the stock is down ~75%.

Very low visibility: Valuation suspended until more clarity

Given the wide range of possible outcomes, from a limited data request to a full new trial, and no disclosure yet on the specific deficiencies cited by the FDA, visibility on the path forward is too low to assess. Our valuation is therefore suspended until there is more clarity.

Fast comment

Commissioned research

Not rated

Healthcare

ACE-SE/ACE SS

Share price (SEK)	2/7/2026	0.78
MCap (SEKm)		103
MCap (EURm)		9
No. of shares (m)		133.5
Free float (%)		96.2

Next event Q2 report 20 August 2026

Analyst:
georg.tigalonov-bjerke@abgsc.no, +47 22 01 60 84

SEKm	2024	2025	2026e	2027e
Sales	0	0	78	75
Sales growth (%)	--	--	--	*-4.3*
EBITDA	-68	-74	10	15
EBITDA margin (%)	--	--	*13.4*	*19.7*
EBIT adj.	-68	-74	10	15
EBIT adj. margin (%)	--	--	*13.4*	*19.7*
Pretax profit	-80	-77	11	14
EPS	-0.83	-0.60	0.09	0.10
EPS growth (%)	*-74.3*	*-28.4*	*nm*	*17.4*
EPS adj.	-0.83	-0.60	0.09	0.10
DPS	0.00	0.00	0.00	
EV/EBITDA (x)	-0.4	-0.7	2.1	0.6
EV/EBIT adj. (x)	-0.4	-0.7	2.1	0.6
P/E (x)	nm	nm	8.9	7.6
P/E adj. (x)	nm	nm	8.9	7.6
EV/sales (x)	--	--	0.28	0.11
FCF yield (%)	-84.4	-73.0	11.7	13.1
Le. adj. FCF yld. (%)	-85.6	-73.8	11.5	12.9
Dividend yield (%)	0.0	0.0	0.0	0.0
Net IB debt/EBITDA (x)	0.7	0.7	-7.9	-6.5
Le. adj. ND/EBITDA (x)	0.7	0.7	-8.0	-6.6

Source: ABG Sundal Collier, Company Data

Analyst Certification

We, Georg Tigalonov-Bjerke and ABGSC Healthcare Research, analyst(s) with ABG Sundal Collier ASA , ABG Sundal Collier Denmark, filial af ABG Sundal Collier ASA, Norge, ABG Sundal Collier AB and/or ABG Sundal Collier Limited (hereinafter collectively referred to as “ABG Sundal Collier”), and the author(s) of this report, certify that not withstanding the existence of any such potential conflicts of interests referred to below, the views expressed in this report accurately reflect my/our personal view about the companies and securities covered in this report. I/We further certify that I/We has/have not been, nor am/are or will be, receiving direct or indirect compensation related to the specific recommendations or views contained in this report.

This report is produced by ABG Sundal Collier, which may cover companies either in accordance with legal requirements designed to promote the independence of investment research (“independent research”) or as commissioned research. Commissioned research is paid for by the subject company. As such, commissioned research is deemed to constitute an acceptable minor non-monetary benefit (i.e., not investment research) as defined in MiFID II.

Analyst valuation methods

ABG Sundal Collier analysts may publish valuation ranges for stocks covered under Company Sponsored Research. These valuation ranges rely on various valuation methods. One of the most frequently used methods is the valuation of a company by calculation of that company's discounted cash flow (DCF). Another valuation method is the analysis of a company's return on capital employed relative to its cost of capital. Finally, the analysts may analyse various valuation multiples (e.g. the P/E multiples and the EV/EBITDA multiples) relative to global industry peers. In special cases, particularly for property companies and investment companies, the ratio of price to net asset value is considered. Valuation ranges may be changed when earnings and cash flow forecasts are changed. They may also be changed when the underlying value of a company's assets changes (in the cases of investment companies, property companies or insurance companies) or when factors impacting the required rate of return change.

Expected updates

ABGSC has no fixed schedule for updating its research reports. Unless expressly stated otherwise, ABGSC expects (but does not undertake) to issue updates when considered necessary by the research department, for example following the publication of new figures or forecasts by a company or in the event of any material news on a company or its industry.

Important Company Specific Disclosure

The following disclosures relate to the relationship between ABG Sundal Collier and its affiliates and the companies covered by ABG Sundal Collier referred to in this research report.

Unless disclosed in this section, ABG Sundal Collier has no required regulatory disclosures to make in relation to an ownership position for the analyst(s) and members of the analyst's household, ownership by ABG Sundal Collier, ownership in ABG Sundal Collier by the company(ies) to whom the report(s) refer(s) to, market making, managed or co-managed public offerings, compensation for provision of certain services, directorship of the analyst, or a member of the analyst's household, or in relation to any contractual obligations to the issuance of this research report.

ABG Sundal Collier has undertaken a contractual obligation to issue this report and receives predetermined compensation from the company covered in this report.

ABG Sundal Collier acted as Sole Global Coordinator and Bookrunner in connection with the SEK 30 million directed share issue in Ascelia Pharma

ABG Sundal Collier is not aware of any other actual, material conflicts of interest of the analyst or ABG Sundal Collier of which the analyst knows or has reason to know at the time of the publication of this report.

All prices are as of market close on 2 July, 2026 unless otherwise noted.

Disclaimer

This report has been prepared by ABG Sundal Collier ASA, ABG Sundal Collier Denmark, filial af ABG Sundal Collier ASA, Norge, ABG Sundal Collier AB and/or ABG Sundal Collier Limited and any of their directors, officers, representatives and employees (hereinafter collectively referred to as “ABG Sundal Collier”). This report is not a product of any other affiliated or associated companies of any of the above entities.

This report is provided solely for the information and use of professional investors, who are expected to make their own investment decisions without undue reliance on this report. The information contained herein does not apply to, and should not be relied upon by, retail clients. This report is for distribution only under such circumstances as may be permitted by applicable law. Research reports prepared by ABG Sundal Collier are for information purposes only. The recommendation(s) in this report is (are) has/have no regard to specific investment objectives and the financial situation or needs of any specific recipient. ABG Sundal Collier and/or its affiliates accepts no liability whatsoever for any losses arising from any use of this report or its contents. This report is not to be used or considered as an offer to sell, or a solicitation of an offer to buy. The information herein has been obtained from, and any opinions herein are based upon, sources believed reliable, but ABG Sundal Collier and/or its affiliates make no representation as to its accuracy or completeness and it should not be relied upon as such. All opinions and estimates herein

reflect the judgment of ABG Sundal Collier on the date of this report and are subject to change without notice. Past performance is not indicative of future results.

The compensation of our research analysts is determined exclusively by research management and senior management, but not including investment banking management. Compensation is not based on specific investment banking revenues, however, it is determined from the profitability of the ABG Sundal Collier group, which includes earnings from investment banking operations and other business. Investors should assume that ABG Sundal Collier ASA, ABG Sundal Collier Denmark, filial af ABG Sundal Collier ASA, Norge and/or ABG Sundal Collier AB is seeking or will seek investment banking or other business relationships with the companies in this report.

The research analyst(s) responsible for the preparation of this report may interact with trading desk and sales personnel and other departments for the purpose of gathering, synthesizing and interpreting market information. From time to time, ABG Sundal Collier and/or its affiliates and any shareholders, directors, officers, or employees thereof may (I) have a position in, or otherwise be interested in, any securities directly or indirectly connected to the subject of this report, or (II) perform investment banking or other services for, or solicit investment banking or other services from, a company mentioned in this report. ABG Sundal Collier and/or its affiliates rely on information barriers to control the flow of information contained in one or more areas of ABG Sundal Collier, into other areas, units, groups or affiliates of ABG Sundal Collier.

Norway: ABG Sundal Collier ASA is regulated by the Financial Supervisory Authority of Norway (Finanstilsynet)

Denmark: ABG Sundal Collier Denmark, filial af ABG Sundal Collier ASA, Norge, is regulated by the Financial Supervisory Authority of Norway (Finanstilsynet) and the Danish Financial Supervisory Authority (Finanstilsynet)

Sweden: ABG Sundal Collier AB is regulated by the Swedish Financial Supervisory Authority (Finansinspektionen)

UK: This report is a communication made, or approved for communication in the UK, by ABG Sundal Collier Limited, authorised and regulated by the Financial Conduct Authority in the conduct of its business.

US: This report is being distributed in the United States (U.S.) in accordance with FINRA Rule 1220 by ABG Sundal Collier Inc., an SEC registered broker-dealer and a FINRA/SIPC member which accepts responsibility for its content and its compliance with FINRA Rule 2241. Research reports distributed in the U.S. are intended solely for “major U.S. institutional investors,” and “U.S. institutional investors” as defined under Rule 15a-6 of the Securities Exchange Act of 1934 and any related interpretive guidance and no-action letters issued by the Staff of the U.S. Securities and Exchange Commission (“SEC”) collectively (“SEC Rule 15a-6”). Each major U.S. institutional investor and U.S. institutional investor that receives a copy of this research report, by its acceptance of such report, represents that it agrees that it will not distribute this research report to any other person. This communication is only intended for major U.S. institutional investors and U.S. institutional investors. Any person which is not a major U.S. institutional investor, or a U.S. institutional investor as covered by SEC Rule 15a-6 must not rely on this communication. The delivery of this research report to any person in the U.S. is not a recommendation to effect any transactions in the securities discussed herein, or an endorsement of any opinion expressed herein. Any major U.S. institutional investor or U.S. institutional investor receiving this report which wishes to effect transactions in any securities referred to herein should contact ABG Sundal Collier Inc., not its affiliates. Further information on the securities referred to herein may be obtained from ABG Sundal Collier Inc., on request.

Singapore: This report is distributed in Singapore by ABG Sundal Collier Pte. Ltd, which is not licensed under the Financial Advisors Act (Chapter 110 of Singapore). In Singapore, this report may only be distributed to institutional investors as defined in Section 4A(1)(c) of the Securities and Futures Act (Chapter 289 of Singapore) (“SFA”), and should not be circulated to any other person in Singapore.

Canada: This report is being distributed by ABG Sundal Collier ASA in Canada pursuant to section 8.25 of National Instrument 31-103 or an equivalent provision and has not been tailored to the needs of any specific investor in Canada. The information contained in this report is not, and under no circumstances is to be construed as, a prospectus, an advertisement, a public offering or an offer to sell the securities described herein, in Canada or any province or territory thereof. No securities commission or similar regulatory authority in Canada has reviewed or considered this report, the information contained herein or the merits of the securities described herein and any representation to the contrary is an offence. Under no circumstances is this report to be construed as an offer to sell such securities or as a solicitation of an offer to buy such securities in any jurisdiction of Canada. Any offer or sale of the securities described herein in Canada may only be made in accordance with applicable securities laws and only by a dealer properly registered under such securities laws, or alternatively, pursuant to an applicable dealer registration exemption, in the Canadian jurisdiction in which such offer or sale is made.

Additional information available upon request. If reference is made in this report to other companies and ABG Sundal Collier provides research coverage for those companies, details regarding disclosures may be found on our website www.abgsc.com.

Norway
Ruseløkkveien 26, 8th floor
0251 Oslo
Norway
Tel: +47 22 01 60 00
Fax: +47 22 01 60 60

Denmark
Forbindelsesvej 12,
2100 Copenhagen
Denmark
Tel: +45 35 46 61 00
Fax: +45 35 46 61 10

Sweden
Regeringsgatan 25, 8th floor
111 53 Stockholm
Sweden
Tel: +46 8 566 286 00
Fax: +46 8 566 286 01

United Kingdom
10 Paternoster Row, 5th floor
London EC4M 7EJ
UK
Tel: +44 20 7905 5600
Fax: +44 20 7905 5601

USA
140 Broadway, Suite 4604
New York, NY 10005
USA
Tel. +1 212 605 3800
Fax. +1 212 605 3801

Singapore
10 Collyer Quay
Ocean Financial Center
#40-07, Singapore 049315
Tel +65 6808 6082

Germany
Schillerstrasse 2, 5. OG
60313 Frankfurt
Germany
Tel +49 69 96 86 96 0
Fax +49 69 96 86 96 99

Switzerland
ABG Sundal Collier AG
Representative Office
Schwanenplatz 4
6004 Lucerne
Switzerland
Tel +41 79 502 33 39