SwedenBIO's Disclosure Recommendations for Development Stage Companies

Version 1.1

Approved by SwedenBIO's Board on 29 August 2018

SwedenBIO • Wallingatan 24 • 111 24 Stockholm • Tel: 08-21 66 20 • Org.nr: 556644–6398 • www.swedenbio.se

Goal

The goal of this document is to promote the need for investors to be supplied with relevant information, deemed to be of material importance for assessing valuation and the prospects of long term value creation in development stage companies in the field of Life Sciences[1] (e.g. drug development companies in pre-clinical or clinical development stage as well as medical device, technology platform and diagnostics companies in pre-commercial stage) and, through this, contribute to a well-functioning capital market. It is a further ambition of SwedenBIO that referring to this document shall become "good market practice" on the Swedish capital markets in relation to (a) initial public offerings and (b) other financings. In addition, the companies affected by this document are also encouraged to address the information requests outlined in this document in annual reports.

Purpose

The purpose of the document is to encourage development stage companies to clearly address the information requests described in this recommendation in the prospectuses and other documentation produced in relation to financing rounds and distribution of ownership which form the basis for investors' assessments of the company in question (hereinafter referred to as "prospectus like documentation"). The information requests are in addition to the information which a company is obliged to disclose regarding its operations in accordance with the prospectus rules and disclosure requirements from the relevant market place.

The board of directors of the company in question should in prospectus-like documentation clearly account for to what extent the company addresses the information requests found in this recommendation. When such information is not included, if applicable, such items should be specified and an explanation should be provided as to why they are not addressed.

Information Which Should be Addressed in Prospectus Like Documentation

The information requests below shall relate to the company's most significant project and/or product under development. What constitutes a significant project depends e.g. on in which field the company is active in, as well as the overall scope of the company's operations. As a general rule, a company's significant project(s) are projects, or products under development, which have or likely will have, a material importance to the company's valuation and standing on the market, short or long term. The basis for the supply of information in accordance with this document shall be that information, which is deemed to be of significant importance to an investor in making his/her investment decision, shall be provided. If the company has several

[1] This document primarily concerns biotechnology, pharmaceutical and medical technology companies.

SwedenBIO • Wallingatan 24 • 111 24 Stockholm • Tel: 08-21 66 20 • Org.nr: 556644–6398 • www.swedenbio.se

projects, or products under development, which are deemed to be of a significant nature, information shall be provided for all such projects or products under development.[2] The following information concerning the company's **significant project(s)** (see above) (below referred to as "**the Project**") shall be provided:

I. Background

a. Short description regarding where the Project has its background/source (e.g. academic institution, pharmaceutical or biotechnology company).

b. State whether the Project (or any part of the Project) has previously been licensed to a third party.

c. Describe potential third party obligations, e.g. royalty rights and/or other liabilities in favour of third parties.

II. Development stage and financing

a. The Project's development phase
   i. Drug development
      1. Pre-clinical phase (*in vitro, in vivo*, "lead candidate" selected, toxicity tests completed etc.)
      2. Clinical phase (phase I, II or III)
      3. Stage between phase III and registration/marketing approval
      4. Registered and approved for marketing (specify relevant markets)
   ii. Medical devices
      1. Classification of the product in relevant markets (e. g. EU MDR, class I-III, and EU IVDR, class A-D)
      2. The product is in prototype phase, going through functional tests
      3. 0-series is produced as intended for clinical assesment
      4. The product is in clinics for clinical testing
      5. The product is in the process of CE-marking or other regulatory submissions
      6. The product has gone through regulatory requirements e. g. CE, FDA 510K, PMA or CFDA and is approved for sales in a number of countries, which should be specified.

[2] Most commonly, this judgement would be related to development phase in relation to which more advanced projects are deemed to be of a significant nature when estimating value and value creation. This does not rule out that other parameters, which e.g. can relate to other earlier stage projects, are deemed to be equally, or more significant, in relation to the company's total value and/or possible value creation.

b. Describe the next significant value creating and risk mitigating event concerning the Project.

c. Assessment of the approximate time needed until the next significant value creating and risk mitigating event concerning the Project.

d. Assess, to the extent possible, the approximate capital need[3] to get to the next significant value creating and risk mitigating event for the Project and account for the major underlying assumptions.

e. Whether the company after completed initial public offering and/or financing is fully financed in order to reach the next significant value creating and risk mitigating event concerning the Project.

f. Estimated capital need[2] to complete registration and marketing approval/authorisation in the EU and/or the US concerning the Project. Describe the strategy how to take the Project to the market (e.g. if the strategy assumes licensing) and assess, to the extent possible, capital needed for the project/product to reach market.

III. Regulatory Process for Approval

a. Provide a short description regarding the expected clinical study program needed for approval/registration concerning the Project (e.g. double blind study vs. standard of care or placebo, ”non-inferiority”/”superiority”).

b. In relation to medical technology products, specify relevant regulatory framework and process[4].

c. Provide an overview of decisions and material statements from regulatory authorities (e.g. the FDA och EMA) which are deemed to have a direct or an indirect significant effect on the Project.

IV. Regulatory Process for Reimbursement

a. Shortly describe the overall expected principles and timelines for achieving reimbursement from healthcare providers, payors, insurance programs etc. in the

[3] Capital need shall be stated as the company’s total capital need up until and including such event and e.g. include expeses for clinical development, overhead and fixed expenses and expenses for ”CMC” (Chemistry, Manufacturing & Controls).
[4] E.g. if the US regulatory approval will fall under a so called 510k or PMA and what class of medical device the company’s product is expected to belong to

SwedenBIO • Wallingatan 24 • 111 24 Stockholm • Tel: 08-21 66 20 • Org.nr: 556644–6398 • www.swedenbio.se

most important markets (e.g. the five largest markets/countries) as well as, if applicable, whether it is expected that patients will pay (self-pay) for purchase/treatment with the product in question.

V. Market Estimates

a. Describe the approximate assumptions relating to the assessment of potential market size (no of procedures/treatments and estimated value/annual sales) that the Project can address (e.g. the five largest markets). Also describe important forces and barriers for the Project/Product to be successful the market and give a picture which segments or parts of the market that the Project can address and how the Project/Product is planned to reach the market.
b. Mention if possible similar competing Projects/Product.

VI. Patents and Other Intellectual Property Rights

a. Describe the patents concerning the Project which the company holds, patent applications as well as information regarding which type of patents and patent applications (e.g. substance or use/indication patents) which are relevant. Also provide territorial scope.

b. Describe other significant immaterial rights (e.g. data exclusivity, orphan drug designation, trade marks) that the company holds or needs for the development and commercialization of the Project.

c. Describe patent terms including how long after estimated product launch the assumed patent protection will exist relating to the Project.

d. If a so called FTO[5] analysis has been completed, describe its conclusions.

About SwedenBIO

SwedenBIO works towards creating a competitive life science sector in Sweden. We do so by establishing effective dialogs between the different actors in the sector, building knowledge and providing the sector with a strong voice.

SwedenBIO represents the leading life science companies in Sweden. Our 250 members are companies active within pharma, biotech, diagnostics and medtech and comprise the entire range from small start-ups, to SMEs and large enterprises. Many are engaged in research and

[5] Freedom to Operate, i.e. whether the Project may be deemed to interfere with third party patents or immaterial property rights.

development. Other members are experts in fields such as IP, law, finance, product development, life science communication and business development.

Contact details

Jonas Ekstrand, Director General
SwedenBIO
Wallingatan 24
11124 Stockholm

Email: jonas.ekstrand@swedenbio.se
Telefon +46(0)8-21 66 20