LIFE SCIENCE DEVELOPMENT STAGE
COMPANY ACCOUNTING
Early development stage companies need to focus their attention on developing their scientific research and would prefer not to have to spend a lot of time and money on the finance and accounting function. However, when it comes to raising equity capital or debt financing, quality financial statements can mean the difference between getting funding and staying in business or going out of business.

For life science companies, early success means passing the hurdle of securing FDA approval. Obtaining FDA approval is the ultimate reward for all the hard work during the research and development phase. However, there are other key areas that management should pay attention to during the development stage phase, and one of these is the accounting for significant and complex transactions.

**Considerations for Life Science Companies Under the Development Stage**

Life science companies face numerous accounting and finance issues including debt and equity capital, development stage reporting, clinical trials, and research and development expenditures, as well as other areas. Due to the tight budgets and regulatory issues these companies face, resources may not always be focused on quality finance personnel. The lack of an experienced accounting team may lead to recordkeeping issues in the beginning of a company’s life cycle. This could lead to problems if the company needs a financial statement audit.

**Capital Financing, Stock-Based Compensation and Valuation**

Development stage companies may be required to have a financial statement audit done by an independent accounting firm. Venture capitalists, commercial banks and other shareholders that infuse capital or loan money into the company also may require an annual audit.
Since most companies have not generated any revenues from operations, funding from these sources is critical in getting the company started and through the commercialization of its product. However, obtaining debt financing or a capital infusion is not easy these days. As development stage companies have no track record and the success of the company’s product cannot be determined, venture capitalists and investors usually require higher interest payments or a significant amount of ownership in the company to compensate for the risk that comes with a development stage company.

Some of the types of loans and capital issued to investors include debt convertible to common stock, preferred stock issued with warrants, and redeemable preferred stock with warrants. The accounting for these transactions can be complicated. For example, if a conversion feature to common stock related to debt has a lower price than the company’s fair value stock price upon issuance, additional interest expense would have to be recorded on the income statement as it is switched from debt to equity. If preferred stock issued has a redeemable option for cash to the investor, the company may have to determine whether the preferred stock should be classified as a liability (i.e. mezzanine treatment) rather than equity in the balance sheet.

Warrants to purchase company stock that are issued with debt may also create accounting issues in determining the correct fair value, account for the warrants as debt discount or debt issuance cost, and determine if the warrant needs to be classified as a liability versus equity.

For example, one company that we audited entered into a loan and security agreement with a lending company. The lending company was also granted warrants to purchase preferred shares. Upon our review of the warrant agreement, it was noted that the lending company may convert the warrant into a determinable number of preferred shares in lieu of exercising the warrant in the future. Due to the fact that the issuer of the warrants may be required to convert
the warrants into shares, the issuer reported the warrants at fair value using the black-scholes option pricing model (which is used to calculate fair value using various input assumptions) and classified the warrants as a liability.

Development stage companies grant stock options to employees with a promise to sell the company’s stock at a pre-determined price in exchange for working with the company for a certain period of years. Such stock options are usually recorded as stock-based compensation at its fair value over the requisite service period. Determining fair values of both warrants and stock options normally require a black-scholes calculation through the use of an IRC 409(a) valuation input.

**Required Financial Statements Presentation**

When development stage entities have an audit done, there are specific financial statements reporting requirements that must be followed to comply with U.S. Generally Accepted Accounting Standards (GAAP). Accounting Standards Codification 916 – *Development Stage Entities* defines a development stage entity as “an entity devoting substantially all of its efforts to establishing new business.”

Two types of conditions exists for these companies that fall under the definition of development stage; (1) The company is focused on research and development and no product has been released for sale; or (2) The company has sold their main product but revenues are minimal and the success of the product is uncertain. Financial statements for such entities are prepared and presented in the same manner as those of an operating entity, but the financial statements have to be identified as a development stage enterprise. In addition, the statements of operations, stockholders’ equity and cash flows, should include an additional column reflecting cumulative amounts from the company’s inception to date of profit and loss, cash flows and shareholder equity transactions. Also, a description of the development activities and all the issuance of stock options and warrants, along with the prices, should be disclosed in the footnotes.
One of our clients waited to be audited for the first time, but had been incorporated for five years prior to the start of the audit. We advised them on the reporting requirements they face as the principal operations had not yet commenced. This required them to obtain records from up to five years prior to the fiscal year end for us to audit and present in the financial statements. This is especially difficult in the common stock valuation area if options have been granted over a long period of time and you need to record the fair value of the stock based compensation expense, starting on the year the options were granted. Since they were not aware of the presentation requirements, they incurred additional time and effort in getting the records together. Due to the comprehensive disclosures required, companies may find it challenging if its accounting records are not managed properly in the beginning stages of its life cycle.

**Accounting for Clinical Trials**

For a development stage company to commercialize its product and pass government regulations, most pharmaceutical and medical device companies must test their products through clinical trials. During clinical trials, medical devices or drugs are tested to ensure the product is safe and is working the way it was intended and designed. The data that is generated from the clinical trial testing is gathered for the regulatory organizations to be approved for commercialization.

Due to testing performed in patients and several series of trials that may take time, development stage companies may incur sizable costs for the clinical trial process. For many development stage companies, this is their single most expensive activity. Clinical trials are normally managed outside the organization by a contract research organization (CRO). Based on our experience working with Life Science companies, we have found the high cost of clinical trial activities and the fact that the process is managed outside the company creates a high risk of misstatement in the financial statements. Specifically, we have seen problems in accounting for the completeness of the amount owed to the CRO.
For example, CROs may require payments in advance of performing services and the payments are nonrefundable. On the flip side, services may have been performed by the CRO, but billings for services have not been sent to the development stage company. One company that we performed audit services for hired a CRO to test their product. The contract with the CRO required payments to be due upon certain milestones being met, such as the number of patients tested. Determining the accrual due to the CRO may be challenging if the company has not yet received the billing from the CRO. We recommended that the development stage company record clinical trial expenses in its financial statements in the period the services were performed. In the case where an invoice was not received, an estimate would be made based on the number of patients enrolled, number of sites, and how much work was completed to date. This accounting involves judgment to ensure that the entire amount owed to the CRO is properly accrued at period end.

**Accounting for Research and Development and Pre-Launched Inventories**

As noted earlier, development stage companies do not have significant revenues generated from operations. Therefore, the company is mainly incurring expenses such as research and development (R&D) costs. For financial statement and tax purposes, development stage companies must be aware of which costs can be classified as research and development. Accounting Standards Codification 730 (ASC 730) – *Research and Development* states that “R&D includes those activities aimed at developing or significantly improving a product or service or a process or technique whether the product or process is intended for sale or use.” For those companies in the life sciences industry, R&D costs would consist of materials, supplies and personnel expenses incurred that directly relate to the pre-commercialized product. All costs related to R&D are charged to expense when incurred. One common pitfall we see is that companies charge patent legal costs to R&D instead of general and administrative expense which is required under ASC 730.
Upon the commercialization of a product, when significant revenues have been earned by the company, the entity is no longer considered in the development stage. Typically, fully operating companies have no major redesign or developments on the main product lines and are mainly focused in the production of its products for sale. It is during this stage that companies start capitalizing production costs as inventories and charging it to cost of sales when sold.

Audited financials must be in compliance with U.S. GAAP. If development stage reporting issues are not addressed early, significant amount of time and effort will be spent in correcting the accounting for such transactions.

**Update**

On September 11, 2013, Financial Accounting Standards Board (FASB) voted to issue an exposure draft containing proposals intended to improve financial reporting on public and private development stage entities.

The exposure draft is based on recommendations of the Private Company Council. Stakeholders have raised concerns about the cost and relevance of additional presentation requirements. Most companies in the life sciences industry do not commercialize their products for several years and some companies eventually sell their R&D to other companies. Therefore, they have been impacted by the existing reporting requirements for a long period of time.

A final exposure draft is expected to be released by FASB later in 2013. An article summarizing the exposure draft and how it could impact development stage companies will be prepared by BPM once the exposure draft is issued.
About the Authors

Jerome Lansangan is an Assurance Manager and Wesley Mintu is an Assurance Senior Manager at Burr Pilger Mayer, Inc., the largest California-based accounting and consulting firm where they are members of the Life Sciences Industry practice. Jerome works closely with medical device companies and can be reached at jlansangan@bmpcpa.com. Wesley works primarily with public and private life science companies and can be reached at wmintu@bmpcpa.com.