MOSS-ADAMS LLP

Certified Public Accountants | Business Consultants

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Under the Microscope

An Analysis of SEC Comment Letter Trends Among Middle-Market and Pre-IPO Life Sciences Companies

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Introduction

We've seen a flurry of initial public offerings in the life sciences industry over the past year and a half. After a period that saw an average of barely a dozen each year, in 2013 the number jumped to 50 as of the first week of December, with the collective capital raised reaching $6.8 billion. Following a brief cooldown period in autumn 2013, the first quarter of 2014 once again brought activity to a fever pitch, with 32 life sciences companies completing IPOs in various US exchanges by the end of March.

Interestingly, this positive mood was also evident in strong post-IPO performances. Newly listed public life sciences companies recorded an average return of 38.3 percent as of December 2013, outpacing the Dow Jones Industrial Average (22.8 percent), the S&P 500 (26.6 percent), and the NASDAQ Composite Index (34.5 percent).

While a combination of macroeconomic and regulatory drivers are responsible for the acceleration of IPOs, a resurgent stock market and lower interest rates have created a friendlier economic environment for companies seeking to go public. The performance of the life sciences industry on the whole too has been impressive. What's more, the 2012 JOBS Act has significantly eased the IPO process, and a more efficient FDA approval process has resulted in faster growth for a number of companies.

This euphoria is resulting in a raft of new registrants on US exchanges, many of whom have yet to reach operational maturity. For these companies, there's an impending need to not only be aware of but also understand and learn from accounting issues that have proved challenging for their peers and have been a focus of scrutiny by the SEC.

To help, Moss Adams LLP has researched trends in the nature of comments made by SEC staff toward life sciences companies' financial filings. We've compiled the results in this report, breaking the data down by market capitalization and subindustry and providing sample comments by the SEC to further illuminate the nature of the queries.

The goal is to provide less operationally mature middle-market life sciences companies (those with current market capitalizations of less than $2 billion), as well as pre-IPO life sciences companies looking to go public, with actionable data as they prepare their SEC filings, be they S-1s, 10-Ks, or 10-Qs.

We hope you find this information useful. Please contact us if you have any questions about the content in this report or would like assistance as you prepare your filings.

ERIC MILES, PARTNER
National Practice Leader, Life Sciences
(408) 916-0571
eric.miles@mossadams.com

RICHARD CROGHAN, PARTNER
Northern California Practice Leader, Life Sciences
(415) 677-8282
richard.croghan@mossadams.com

FINDLEY GILLESPIE, PARTNER
Washington State Practice Leader, Life Sciences
(206) 302-6212
findley.gillespie@mossadams.com

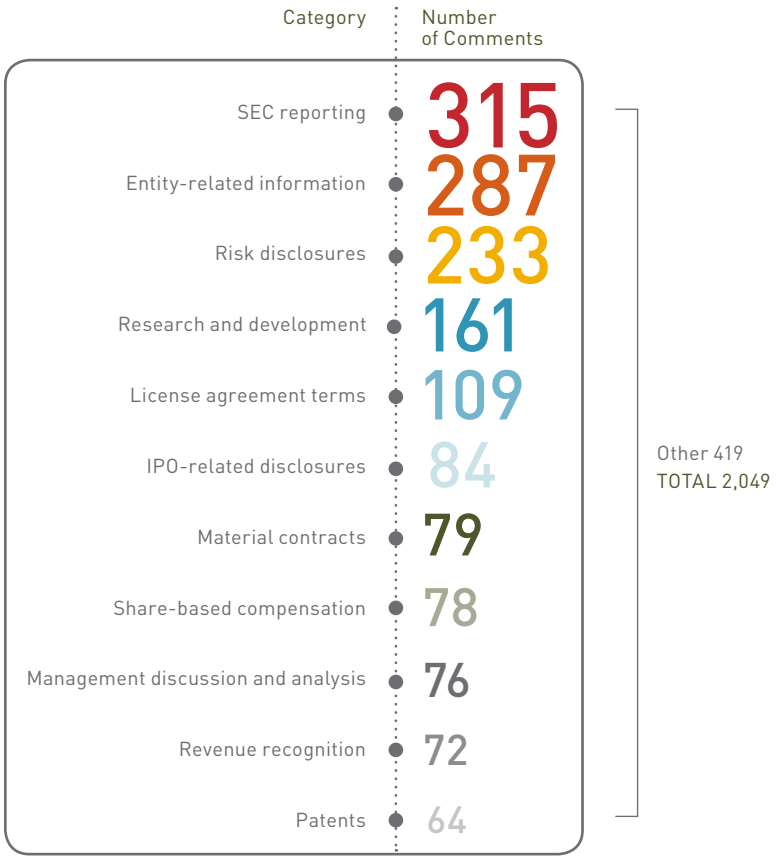
CARISA WISNIEWSKI, PARTNER
Southern California Practice Leader, Life Sciences
(858) 627-1402
carisa.wisniewski@mossadams.com

Executive Summary

For this report, we analyzed major trends in life sciences companies' SEC filings from February 17, 2013, to May 1, 2014, categorizing SEC comments made during this time and noting the frequency of comments made in each category. The infographic below provides an overview of the results of this analysis across all report types, market capitalization ranges, and subindustries.

As it's plain to see, disclosures on entity-related information—such as products and services, legal structure, major collaborations, market environment, and regulations—were one of the SEC's more significant areas of focus during the period of our review.

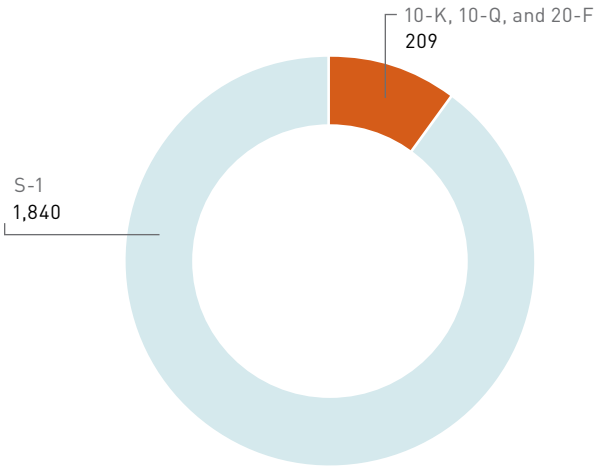
OVERVIEW OF SEC COMMENT CATEGORIES



This was closely followed by disclosures about risk, research and development, terms of license agreements, share-based compensation, and management discussion and analysis (MD&A). Other categories (in particular, SEC reporting, IPO-related disclosures, and material contracts) featured prominently as well, though most comments in these categories were more standard and formulaic (such as requesting the filing of material contracts or other material).

Results by Report Type

NUMBER OF COMMENTS BY REPORT TYPE

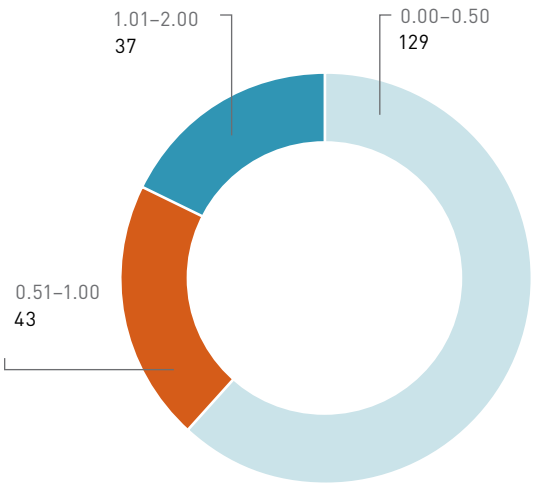


Of the 2,049 SEC comments we analyzed, the vast majority—1,840 (90 percent)—were directed toward S-1 reports (or draft registration statements). This indicates a relatively higher level of scrutiny for companies registering to launch IPOs, which possibly also reveals the correlation between companies' level of operational maturity and their reporting standards.

The areas of the SEC's focus varied considerably among S-1 reports and 10-K, 10-Q, or 20-F reports, with the SEC placing greater focus on post-IPO companies' revenue recognition policies, MD&A, patent-related disclosures, terms of license agreements, and financial statement classification. For pre-IPO companies, the key areas of focus included entity-related information, disclosures about risk, R&D, and share-based compensation.

Results by Market Capitalization Range

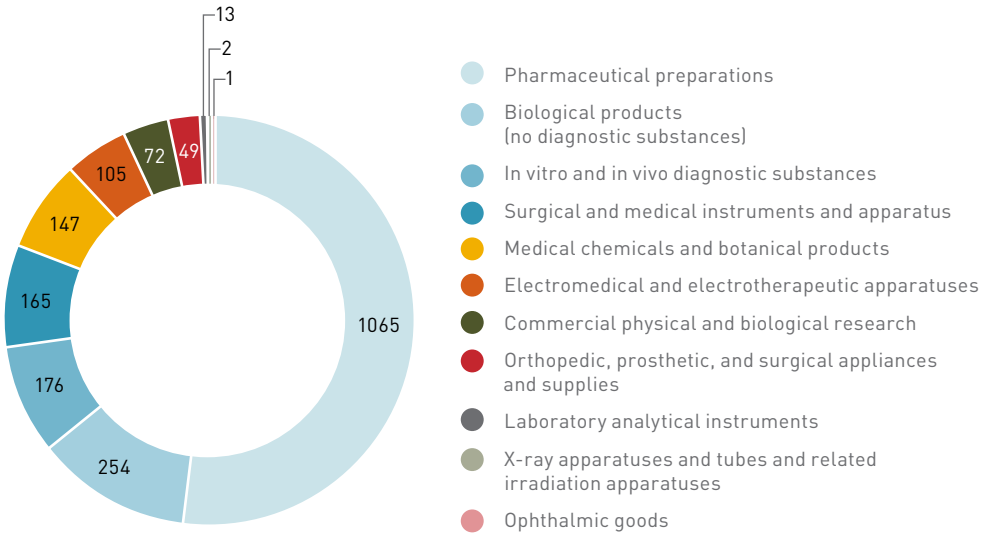
NUMBER OF COMMENTS BY MARKET CAPITALIZATION (FOR PUBLIC COMPANIES ONLY, IN BILLIONS OF DOLLARS)



The majority of SEC comments toward public companies were directed at those with market capitalizations below $500 million, indicating a relatively higher level of scrutiny toward companies in earlier growth stages. Nonetheless, trends in the frequency and types of comments remained more or less consistent across the market capitalization spectrum.

Results by Subindustry

NUMBER OF COMMENTS BY SUBINDUSTRY



More than 50 percent of all comments analyzed (1,065 of 2,049) were directed toward pharmaceutical preparations companies. This is commensurate with the pharmaceutical industry's overall share of the life sciences sector. While the results of our analysis showed fairly consistent trends across most subindustries, there are some variances.

For example, the SEC placed a relatively stronger focus on disclosures of risks in the medical chemicals and botanical products subindustry. Similarly, in the commercial physical and biological research subindustry, revenue recognition was the subject matter of greater focus. Equally significant was the focus on R&D disclosures from pharmaceutical preparations companies compared with other subindustries.

Methodology

Our analysis entailed categorizing all comments in SEC comment letters to companies in select life sciences subindustries during the period of our review. We identified subindustries based on their corresponding SIC codes in the SEC's EDGAR database:

- 2833: Medical chemicals and botanical products
- 2834: Pharmaceutical preparations
- 2835: In vitro and in vivo diagnostic substances
- 2836: Biological products (no diagnostic substances)
- 3826: Laboratory analytical instruments
- 3841: Surgical and medical instruments and apparatuses
- 3842: Orthopedic, prosthetic, and surgical appliances and supplies
- 3843: Dental equipment and supplies
- 3844: X-ray apparatuses and tubes and related irradiation apparatuses
- 3845: Electromedical and electrotherapeutic apparatuses
- 3851: Ophthalmic goods
- 8731: Commercial physical and biological research

For the sake of simplification and relevance, we considered comments relating to the following SEC filings:

- S-1 and draft registration statements
- 10-K
- 10-Q
- 20-F

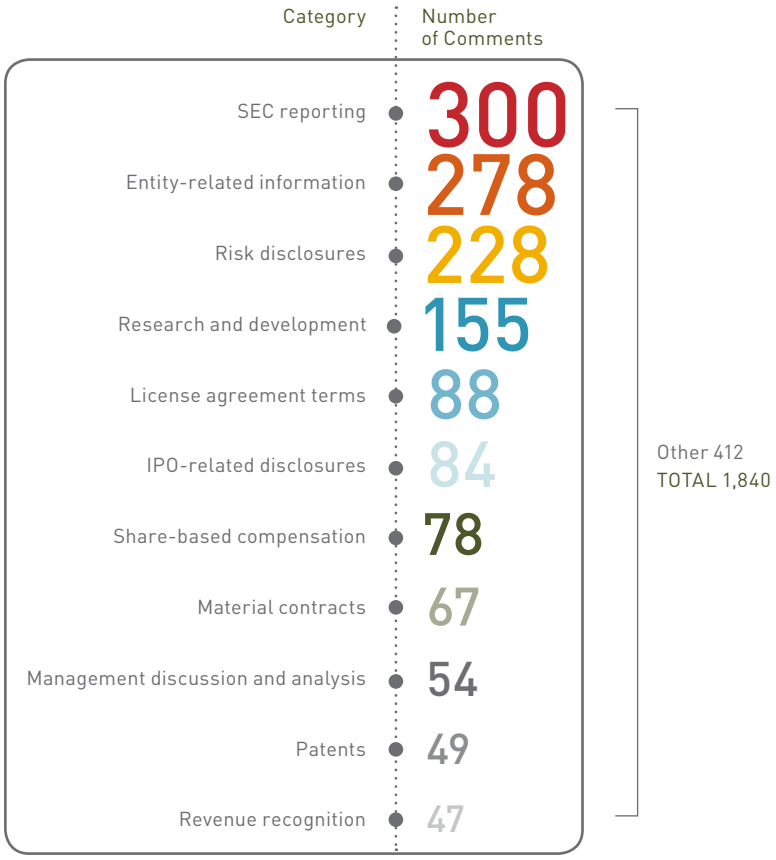
Our objective was to analyze trends in middle-market companies, so we excluded public companies with market capitalizations (on the date of analysis) of more than $2 billion from our research and assessment. Furthermore, we considered only the first instance of an SEC comment letter issued for an individual filing. We did so to make this a fair and objective assessment and to minimize getting skewed results—in most cases second or third iterations of SEC comment letters contain comments of similar nature to those found in the first iteration.

Note also that for the purposes of this report, some of the SEC comments have been edited for space considerations. We've also omitted identifiable information, such as company and product names, dollar figures, and place names, in the SEC's comments.

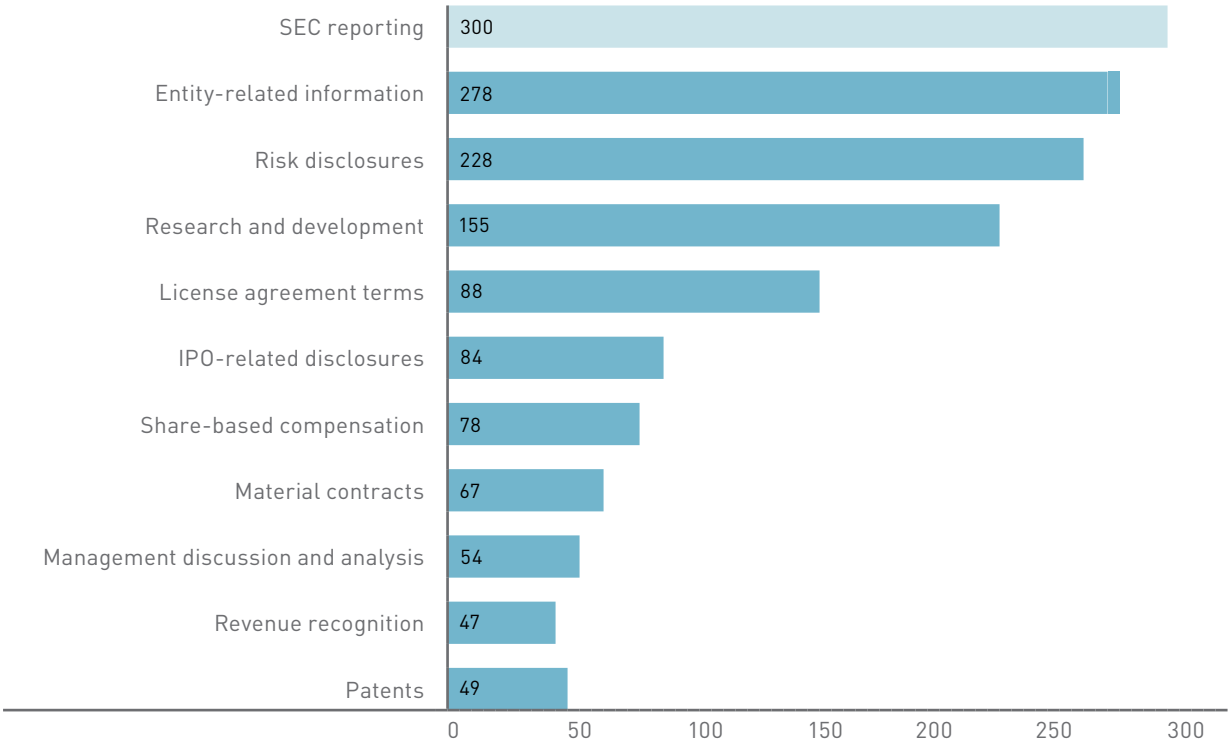
Trends in S-1 Reports

During the period of our analysis, the SEC placed significantly greater scrutiny on S-1 filings than 10-K, 10-Q, and 20-F filings. Indeed, on average, nine out of 10 SEC comments were directed toward S-1 reports.

SEC COMMENT CATEGORIES FOR S-1 REPORTS

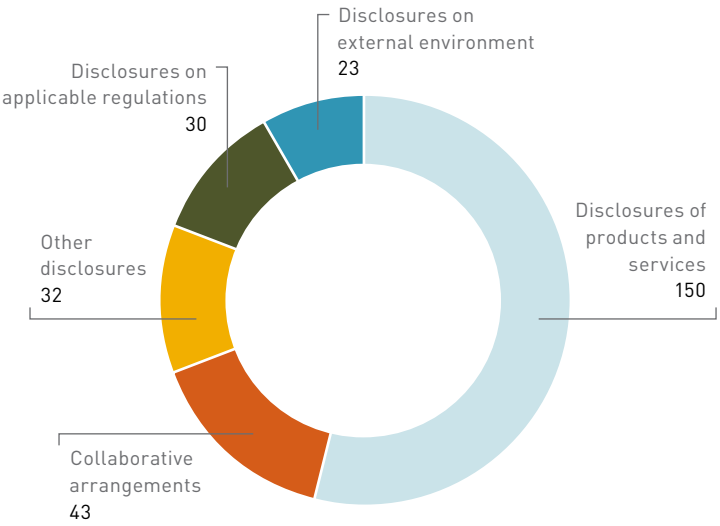


KEY AREAS OF SEC FOCUS FOR S-1 FILINGS (BY FREQUENCY OF COMMENTS)



Entity-Related Disclosures

NUMBER OF COMMENTS BY ENTITY-RELATED SUBCATEGORY



Disclosures on entity-related information were one of the SEC's most common areas of comment for S-1 filings. While they're not formally defined by Regulation S-K, we've grouped certain nonfinancial disclosures that related to the registrants' internal environment (such as products and services, legal structure, and major collaborations) and external environment (such as market demand, competition, and applicable regulations). Comments in this category were largely directed to a variety of standard S-1 items, including prospectus summary, risk factors, and description of business.

Products and Services

Comments related to disclosures of details on products and services provided accounted for a majority of entity-related comments, indicating that these disclosures need to be more informative. For companies in the medical chemicals and botanical products and surgical instruments fields, the SEC has also provided guidelines while requesting more detailed disclosures on how products can be expected to perform "as advertised" and conform to a claimed "unique selling proposition."

Besides this the SEC has also requested additional clarifications along with the identification of potential product side effects and specific risks relating to pharmaceutical preparations. It also appears that the SEC's expectations are that companies will provide objective statements or those that otherwise can be supported independently.

A key takeaway for aspiring registrants in the life sciences industry is the relatively high importance the SEC is placing on accurate, precise, and thorough descriptions of products and services intended for sale. Claims for competitive advantages must be backed up by rationale and data rather than conjecture, and potential risks to consumers need to be clearly disclosed and more detailed.

SAMPLE COMMENTS

- Please provide objective, independent support for your statements regarding the superior or unique design and performance of your insulin pump. For example, we note your statements that [product name] is the "slimmest and smallest durable insulin pump on the market" and that it is "capable of delivering the smallest increment of insulin to users of any pump currently available."
- We note that you instructed your manufacturer to apply a six-stage fermentation manufacturing process on all your enzymes products and that this creates "the unique feature as well as superior quality in certain key parameters" of those products. Please expand your disclosure to discuss the differences between a six-stage fermentation manufacturing process versus the one-stage traditional method. Also, please explain what you mean by the "unique feature" of your products and their "superior quality in certain key parameters."
- In your discussion of your product candidates, you refer to the fact that current therapies are associated with numerous systemic and serious side effects. In some cases you specify certain side effects that have been linked with existing treatments, but in other cases you refer to significant side effects in only general terms. Please revise your draft registration statement to disclose the specific side effects to which you refer when discussing the limitations of current treatments. In addition, when you discuss the safety profile of your product candidates or compare them to the safety of other treatments, please disclose any serious side effects that have been observed in your trials.

Collaborative Arrangements

Life sciences companies in fields such as laboratory analytical instruments, surgical and medical instruments, and prosthetic appliances often have a variety of collaborative arrangements with manufacturers, designers, and distributors. The nature of these arrangements can have a material impact on a company's operational health and financial position, which appears to be one of the main reasons for the SEC to place a strong focus on this area in its comments on S-1 filings.

The SEC has in various instances requested confirmation of the identity of partners such as manufacturers. In several comments the SEC has also inquired about the status of ongoing discussions with prospective partners and expected timelines for the consummation of those discussions. In cases where companies have confirmed the existence of a partnership, the SEC has asked for additional details relating to the obligations agreed upon by the partners, compensation terms, and termination agreements and has requested that such agreements be filed as exhibits.

SAMPLE COMMENTS

- You state that the company contracts with major manufacturers of food products to produce its product. Please describe the nature of your contracts or arrangements with these manufacturers and file such contracts as exhibits to your registration statement.
- Please provide further description of your discussions with "several distributors" that have indicated an interest in distributing the product. Disclose when you expect to consummate such discussions and how and when you estimate you will be able to provide finished product to fulfill such agreements. In addition, please affirmatively state, if true, that you have no written agreements or arrangements with any distributors at this time.
- We note that you have a verbal agreement with [company name] to manufacture and label your products. Please provide more detailed information as to what [company name] has obligated itself to do on your behalf and how you will compensate them. If you enter into a material manufacturing or supply agreement with [company name], please promptly file it as an exhibit either to the registration statement or to the first periodic report you file after entering into the agreement.

Applicable Regulations

Item 101 of Regulation S-K requires new registrants to disclose the "effect of existing or probable governmental regulations on the business." According to our analysis, a significant number of SEC comments related to additional disclosures on regulations that may have a material impact on the business, such as foreign regulations in the case of overseas manufacturing or distribution. These included, for example, requests for details on social insurance regulations in Taiwan or pharmaceutical approval processes in foreign bodies such as the European Medical Association.

Another topic of focus was the US Supreme Court's decision in Association for Molecular Pathology v. Myriad Genetics as it pertains to intellectual property law for companies involved with genetics R&D.

In view of the SEC's comments, new registrants—particularly those with exposure to international regulations through collaborative agreements, overseas manufacturing, or distribution strategies—must undertake adequate research and analysis of the regulatory exposure by describing not only the relevant processes but also the consequent risk factors.

SAMPLE COMMENTS

- Please describe the mandatory requirement under [country name] laws and regulations to purchase social insurance for your employees. Also, please quantify the amount of social insurance you have obtained for your employees.
- We note that you plan to file for approval of your products in both the United States and Europe. Please revise your disclosure to include a section which describes the regulatory process at the EMA.
- Since it appears that you employ DNA-based science to produce the proteins that are the basis for your discovery platform, please tell us in your response what effect, if any, the US Supreme Court's decision in Association for Molecular Pathology v. Myriad Genetics has had or will have on your research and your ability to protect your intellectual property. Please provide any related disclosure involving the decision, to the extent applicable, in the relevant risk factor.

External Environment

The SEC continues to constructively challenge business claims relating to their positioning and the external environment. Comments relating to businesses' competition and market demand appeared prominently during the period under analysis. According to Item 101 of Regulation S-K, registrants are required to disclose in their business description "competitive conditions in the business involved, including, where material, the identity of the particular markets in which the registrant competes, an estimate of the number of competitors, and the registrant's competitive position, if known or reasonably available to the registrant."

New registrants should pay particular attention to the accuracy of market analysis and competitive benchmarking and avoid making tall claims on any uniqueness in their business that can't be defended. In addition, the markets that businesses claim to operate in should be defined with appropriate scope and reference points.

SAMPLE COMMENTS

- We note your statement that "at the present time there is no other sports drink on the market that has no calories, sugar, or carbs." Please reconcile this disclosure with your statement that "there are many similar products available in the marketplace" and, in light of readily available public information regarding market-dominant competitors offering sports drinks with no calories, sugar, or carbs, expand your disclosure to specifically reference PowerAde Zero, MiO, and any other competitive products.
- We note your reference to maintaining a leadership position in the area of visual cycle modulation in this section and throughout the prospectus. Please clarify whether your primary competitors have developed or are developing products in reliance on visual cycle modulation and, if so, why you believe you hold a leadership position in relation

to these entities. Otherwise, please delete your reference to maintaining a "leadership position" in the area of VCM throughout your prospectus.

- You state that the global ADHD therapeutics market was valued at $3.9 billion and is forecast to reach $7.1 billion by 2018. Please revise your disclosure to clarify, if true, that this market includes approved drugs and other products in addition to medical foods. In addition, please expand the discussion to indicate the proportion of the ADHD therapeutics market represented by medical foods.
- We note your citation to a study concerning the market size for mobility device use that was undertaken in 2000 and which relied on data from 1994 to 1995. Please tell us how you determined that this study provides the most recent available information such that it is appropriate to be included.

Risk Disclosures

The SEC continues to place significant emphasis on adequate disclosure of risk factors that are material to new registrants' businesses. Item 503c of Regulation S-K specifically directs registrants to "where appropriate, provide under the caption 'Risk Factors' a discussion of the most significant factors that make the offering speculative or risky. This discussion must be concise and organized logically" and should not include "risks that could apply to any issuer or any offering." Registrants should further "explain how the risk affects the issuer or the securities being offered" and "set forth each risk factor under a subcaption that adequately describes the risk."

Risk factors may include:

- Lack of operating history
- Lack of profitable operations
- Financial position
- Business risks
- Lack of a market for new common equity

You can gauge the SEC's current sentiment from the fact that it asks for risk disclosures to be more specific. Comments encourage registrants to avoid identifying generic risks that could apply to any business and instead focus on comprehensive, transparent, and specific risks associated with their particular circumstances.

For example, a business identifying its dependence on common carrier shipping companies as a risk elicited a comment by the SEC requesting an expanded discussion focusing on the specific risks associated with the registrant's dependence on the carrier as well as a request for a separate risk factor related to shipping price increases. In this case the dependence on a common carrier is a vulnerability and not a risk.

Another trend in SEC comments is the perceived inexperience of senior executives in the businesses' chosen industries. In several cases the SEC directly requested the addition of a risk solely for this purpose on the basis of management profiles that were provided elsewhere in the filing.

The risk of insufficient liquidity was an additional area of focus for the SEC. In cases where businesses identified the risk of requiring additional funds to continue their business plan, the SEC would respond with requests for the disclosure of specifics, such as the amount of working capital on hand, the rate of negative cash flow per month, and a quantification of the fund requirement over a period of 12 months.

Other trends included requests for the addition of risks associated with the procurement of required raw material, conducting operations overseas, and attracting and retaining quality staff.

As a result, as you can see from the SEC's comments, it continues to be important for new registrants to disclose pertinent risks to their business in exhaustive and transparent detail. Specifically, risks related to patents, senior executives' experience and capabilities, and risks related to foreign countries in which a company may operate should be explored, quantified, and disclosed as precisely as possible.

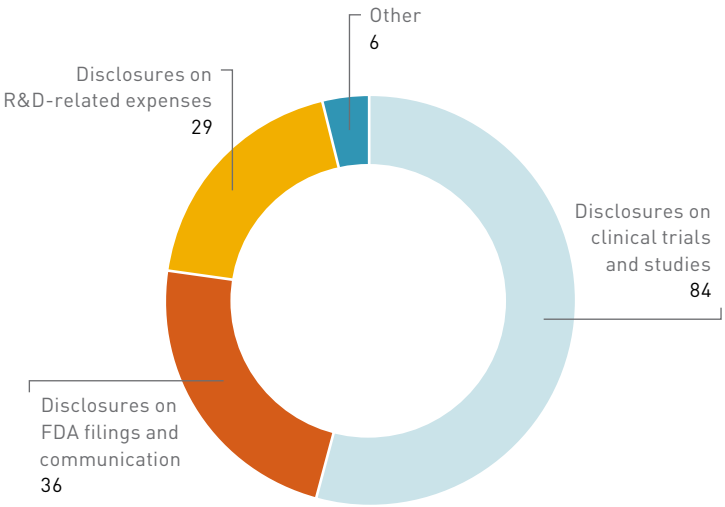
However, new registrants also need to make a clear distinction between a "threat," a "vulnerability," and a "risk." For this purpose it's important to bear in mind that a threat is essentially an event that could cause a risk and that can't be completely eliminated. However, the likelihood of the threat's occurrence can be reduced, and its impact can be mitigated. A vulnerability, on the other hand, is an error or weakness in the design, implementation, or operation of a system that could permit the threat to become a risk. Consequently, a risk is essentially the ground-level scenario in which a vulnerability is exploited for the threat to become harmful.

SAMPLE COMMENTS

- Please revise this section to avoid describing risks in a generic way that could apply to a large number of businesses. Instead include more specific details to clarify the nature of the risks to your company. Provide quantification where possible. For example, the statement "Our business and prospectus must be considered in light of the risks, expenses, and difficulties frequently encountered by companies in their early stages of operation" is too broad and vague and does not address the risks that are particular to your business and operations.
- Please add a risk factor highlighting risks associated with the fact that your executive officers have no experience formulating nutritional supplements or electrolyte-based sports drinks and limited or no experience marketing and selling such products.
- Please expand your disclosure in this section to quantify the amount of your working capital and your rate of negative cash flow per month. In addition, please quantify the amount of funds you will need over the next 12 months as you have done in the section titled "Liquidity and Capital Resources." To the extent practicable, please break out the cost of opening your planned location in [city name].
- We note that you conduct all of your business operations through your operating entity in [country name], whose corporate affairs are governed by its Articles of Incorporation and by the laws governing corporations incorporated in [country name]. Please expand your disclosure to discuss all the material differences between the rights of shareholders and the responsibilities of management and the members of the board of directors for a corporation incorporated under [country name] law as opposed to a corporation incorporated in the Unites States.

Research and Development

NUMBER OF COMMENTS BY R&D-RELATED SUBCATEGORY



R&D constitutes a significant portion of the expenses of life sciences companies, whether in the form of commercial physical and biological research, pharmaceutical preparation, or the manufacture of medical chemicals and botanical products. As a result the SEC has consistently focused on the comprehensiveness of R&D-related disclosures from new registrants. Item 101 of Regulation S-K requires registrants to provide "an explanation of material product R&D to be performed during the period covered in the plan" as well as details on historical R&D expenses.

The focus on R&D continued during the period under our analysis, with 155 comments pertaining to either disclosures on clinical trials and studies, FDA filings and communications, or R&D-related expenses.

Clinical Trials and Studies

Comments related to businesses' clinical trials and studies for their products account for the majority of R&D-related comments. In comments analyzed for this report, the SEC had asked registrants to disclose the current status of clinical trials of each product in their pipeline, details on the effectiveness of the trial process, details on the testing environment, results in each phase of the trials, and the responsible parties for future trials (whether the business entity itself or the product's primary inventor).

The SEC also focused on serious adverse events from clinical trials that may indicate fundamental product deficiencies or lead to significant delays in FDA approvals and product rollouts.

The trends show that life sciences companies aspiring to go public need comprehensive documentation and disclosure on the process, environment, duration, and results (both positive and negative, which need to be described) of clinical trials.

SAMPLE COMMENTS

- Your disclosure states that you have initiated a clinical development program and that you are completing an advanced study in primates for the development of a therapeutic and prophylactic vaccine for treatment and prevention of HIV. Please revise your disclosure to indicate whether such trials were initiated or conducted by your primary inventor or by you and who will bear responsibility for future development and research.
- You state that if the results of the study are statistically and clinically persuasive, [product name] could be considered a Phase 3 study for [product name] in UC and the balance of our registration program could be supported by a single additional Phase 3 induction of clinical remission efficacy study accompanied by a Phase 3 maintenance of clinical remission study. Please clarify your disclosure by providing for comparison the clinical trials that would be required in a non-accelerated case.
- Please specifically describe the adverse events observed during the trial, with particular focus on the serious adverse events. In addition, please explain how you determined that these serious adverse events were not [product name]-related.
- Please expand your disclosure to clarify:
  - The number of subjects in the vehicle and dose 2 groups
  - The number of subjects in the dose 2 group that experienced tumor stasis of up to seven days past the discontinuation of drug treatment
- Please also revise your chart to clarify that the subjects in the dose 2 group received 35 mg/kg per day of [product name], not 25 mg/kg.

FDA Filings and Communication

The SEC continues to comment on inadequate disclosures related to the filing of forms and applications with the FDA. Comments relating to the submission of Investigational New Drug (IND) applications, requests for Special Protocol Assessments (SPAs), and other general communications with the FDA have featured prominently.

In the case of planned distribution in Europe, certain companies were asked to disclose details of their Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA).

SAMPLE COMMENTS

- Please expand your disclosure to indicate whether IND applications were filed for the following product candidates:
  - [Product name] for the treatment of breast cancer
  - [Product name] for the treatment of solid tumors

  If INDs for these product candidates and corresponding indications have been filed, please additionally disclose the identity of the filers and the dates the applications were filed. Alternately, where no IND has been filed, please explain why.

- Please clarify in this section whether you intend to obtain an SPA from the FDA prior to engaging in the Phase 3 [product name] PCI trials. If so, please discuss the current status of that process.
- You disclose that the EMA has advised you of certain matters that may need to be further addressed in your MAA. Please briefly elaborate to give added context to each of the matters to clarify the nature of the FDA's concerns and how you plan to address these in your MAA.

R&D-Related Expenses

Item 101 of Regulation S-K requires new registrants to disclose "if material, the estimated amount spent during each of the last three fiscal years on company-sponsored R&D activities determined in accordance with generally accepted accounting principles" in addition to "the estimated dollar amount spent during each of such years on customer-sponsored research activities relating to the development of new products, services, or techniques or the improvement of existing products, services, or techniques." Smaller reporting companies, as defined by Item 10(f) of Regulation S-K, are required to include an "estimate of the amount spent during each of the last two fiscal years on R&D activities and, if applicable, the extent to which the cost of such activities is borne directly by customers."

Our study shows that the SEC is encouraging new registrants to expand their disclosures of R&D expenses beyond what's required in Item 101 of Regulation S-K. For example, companies may be asked to disclose information on R&D costs by major projects or by program. If a company doesn't provide this information in its filing, it's asked to disclose why.

As a result new registrants should view the guidelines regarding R&D expense disclosures in Regulation S-K as a bare minimum level of disclosure. Tracking and reporting expenses at the project level is becoming the industry norm, regardless of a company's growth stage. For major projects, the SEC increasingly requests further information on development progress. Consequently, registrants need to determine the appropriate level of disclosure and make reasonable estimations on expenses at the project level.

SAMPLE COMMENTS

- We note your statement that the company's founder has developed [product name] over the last 10 years. Please disclose how much he or the company has spent on R&D in the past two years. If no funds have been spent on R&D, please so state.
- You state that R&D activities are central to your business model and that you plan to increase your R&D expenses for the foreseeable future. While you state that you do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis, please expand your disclosure to provide:
  - The costs you do track by project for each period presented and to date and a reconciliation of the total of these project costs to the total expenses presented on your statement of operations and comprehensive loss. In this regard, it appears, for example, that you may track external cost by project as you are able to quantify that [dollar amount] of the increase in R&D expenses in 2012 as compared to 2011 relates to clinical trial expenses for [product name].

  - Explain why management does not maintain and evaluate all R&D costs by project.
  - Explain how you use functional area expenditures to evaluate and prioritize your R&D activities.
  - Explain how you monitor development progress for individual projects.
  - Absent costs by project, please provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on the project such as by stage of development (discovery, pre-clinical, clinical phase I, clinical II, and phase III) and/or other meaningful breakout.
- Please estimate the amount spent on R&D for the past three years ending December 31, 2012, as required by Regulation S-K Item 101(c)(1)(xi).

License Agreement Terms

Companies in the life sciences industry, particularly those in the pharmaceutical preparations and biological products sectors, often have complex licensing agreements with other companies, manufacturers, and educational and research institutions. According to Item 101 of Regulation S-K, registrants are required to disclose in their business description "the importance to the segment and the duration and effect of all patents, trademarks, licenses, franchises, and concessions held."

A majority of the SEC comments here are related to the payment terms of the license. These range from clarifications on up-front payments at the start of the licensing term to aggregate future potential milestone payment obligations. Besides this, the SEC has requested explanations regarding the accounting of the contract and revenue recognition methods applied for each deliverable of the license.

The SEC has also sought details on the material terms of the licenses, including more precise information on the contract terms, royalty obligations, geographical coverage (specifically in cases involving multiple countries), use and other rights, duration, and termination provisions. The SEC has also requested that the license agreements be filed as exhibits to the registration statement pursuant to Item 601(b)(10) of Regulation S-K.

It appears that the SEC is paying special attention to the material terms of the agreement, possibly because these can have a significant impact on the company's business and operations. The right licensing agreement can often be the difference between profit and loss for companies (especially in the life sciences industry), and registrants can benefit by clearly disclosing all financial, termination, and other contractual terms of the agreement.

SAMPLE COMMENTS

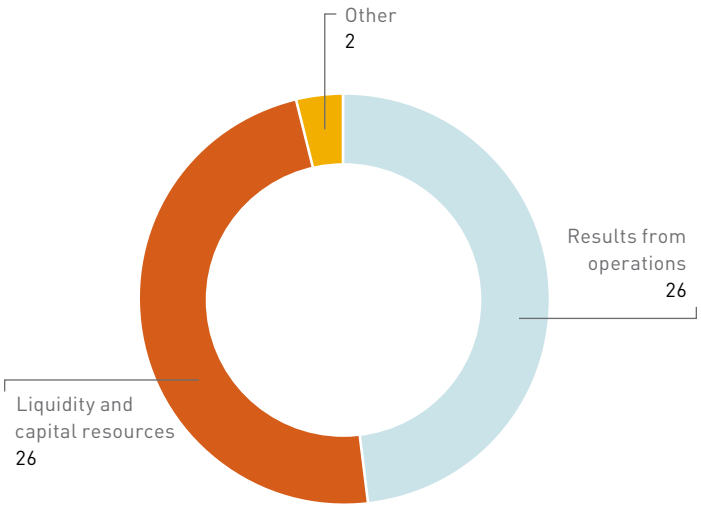
- Please disclose the following additional information in your discussion of this agreement:
  - The specific patents and patent applications licensed to [company name]
  - Any applicable royalty rates
  - Any milestone payment obligations and the aggregate amounts that may be paid or payable under such provisions
  - Material provisions governing duration and termination
  - Any other material provisions, including significant payment obligations

  Please additionally confirm, if true, that any rights retained by [company name] to [product name] and [product name] are limited solely to [country names] and that there are no provisions in the agreement that might allow for any other licensure rights to revert back to [company name].
- You disclose that you retain worldwide rights to [product name]. Please disclose how you were able to reacquire these rights from [company name] and disclose any applicable provisions in the terminated collaboration agreement governing such reacquisition. Additionally, please disclose, if applicable, any retained interest in the product that [company name] may potentially hold.
- We note that you in-license a patent family assigned to [product name]. If this agreement is material to your company, please disclose all of the material terms agreed to by the parties. This includes:
  - Material payment terms, including royalties owed
  - The relevant intellectual property covered and rights conveyed as to such property
  - The duration of the agreement
  - The material termination provisions

  Please file this agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please provide us with an analysis supporting your determination that the agreement is not material to the company.

Management Discussion and Analysis

NUMBER OF COMMENTS BY MD&A-RELATED SUBCATEGORY



MD&A is a key area of focus by the SEC. Item 303 of Regulation S-K requires registrants to provide information on the following five topics:

- Liquidity
- Capital resources
- Results of operations
- Off-balance-sheet arrangements
- Tabular disclosure of contractual obligations

Apart from the above, the regulation also directs a registrant to provide information "necessary to an understanding of its financial condition, changes in financial condition, and results of operations." If interim financial statements are included in the form, then the regulation directs registrants to include in the MD&A the material changes in the financial condition and results of operations for the periods specified in Item 303.

MD&A should provide the reader with an understanding of the operation as well as a financial and analytical view of the company that may not be revealed in the financial statements alone. Most of the comments in the MD&A category have been from either results of operations or liquidity and capital resources.

Results from Operations

Regulation S-K requires that registrants describe any significant known economic changes, trends, or uncertainties and the impact these might have on the company's financial and operational performance. Registrants also need to include any other operational, financial, or related information likely to affect the condition of the company.

Comments in the results from operations section mainly related to the status of product pipelines, product sales, price changes, and cost of goods sold. The SEC in some instances has also requested that registrants further describe and quantify the underlying material factors contributing to significant changes in the results of operations.

What's clear from the comments is that registrants must explain the circumstances and factors that affect the results from operations. Inflation, an increase or decrease in sales, new grants and contracts, and material and labor costs are some examples that can impact the results from operations and consequently must be included in the discussion.

SAMPLE COMMENTS

- We note that you attribute the increase in revenues to both an increase in volume of units rented and average price per rental. In light of the significant increase in revenues, your MD&A disclosure appears broad and does not provide a thorough analysis that provides readers a view of the company through the eyes of management. When individual line items disclosed in your statements of operations significantly fluctuate in comparison to the comparable prior period, management should quantify and disclose the nature of each item that caused the significant change. For example, please quantify each material factor, such as price changes and/or volume changes, separately disclose the effect on operations attributable to each factor causing the aggregate change from year to year, and disclose the nature of or reason for each factor causing the aggregate change. Your revised analysis should discuss the underlying material causes of the factors described as well as the known or expected future impact of any referenced factors on operating results.
- We note that you secured a grant from [company name] in 2011 and, more recently, in 2013 from [company name]. Please expand your disclosure to describe the material terms of these grants, including the amount of the grant, any conditions on funding, obligations under the grants, and the intellectual property rights of each party. Please file any written agreements between the company and [company name] or [company name] as exhibits to the registration statement, as required by Item 601(b)(10) of Regulation S-K.

Liquidity and Capital Resources

Item 303 of Regulation S-K requires registrants to "identify and separately describe internal and external sources of liquidity and briefly discuss any material unused sources of liquidity." The registrant is required to disclose any material commitment and "describe any known material trends, favorable or unfavorable, in the registrant's capital resources."

Comments received in this category related to accounts receivable, cash flows, additional funding requirements, equity financing, and debt. In addition, the SEC has commented on inclusion of previously disclosed items in the table of contractual obligations, advising registrants to use footnotes to disclose the necessary information to facilitate a better understanding of the specified contractual obligations.

It's not surprising that liquidity and capital resources are a focus area for the SEC. Even though the US economy has been showing some signs of growth, cash flows still remain critical indicators of companies' financial health. With financial operating conditions becoming increasingly complex, the SEC is trying to ensure that discussions on liquidity and capital resources are comprehensive and transparent.

SAMPLE COMMENTS

- We note your statement that you do not have sufficient funds for the next 12 months and must raise cash to implement your strategy and stay in business. Please revise to provide a discussion of the extent to which you are actually using funds in your operations on a monthly basis and how much is anticipated to be required to commence intended operations, including a description of any milestones or timelines related to such commencement. Please expand your disclosure to discuss the extent to which you would scale back your development plans if you are unable to raise the additional funds needed.
- Regarding your obligation to make future payments to third parties on the achievement of milestones, please quantify the amount of milestones for each commitment into meaningful categories such as development, regulatory, and/or commercial milestones. In addition, please disclose the nature of the underlying events that trigger the milestone payments.
- You disclose that if you move your principal place of business, your domicile, or certain of your operations outside of [US state], you may be required to repay certain awards or income tax credits. Please revise your disclosure to clarify the terms of the agreements that require you to repay certain awards or income tax credits and the circumstances that do not require repayment. Also, please quantify the amount of awards or income tax credits that you may have to repay.

Share-Based Compensation

Comments related to share-based compensation, specifically those relating to the accounting for stock-based compensation, valuation methods and models, and the use of third-party valuation consultants, all featured prominently in our analysis. The SEC has sought clarifications on the difference between the estimated offering price and the fair value of each equity issuance. Cost of capital used for issuances, vesting requirements, number of shares or equity instruments issued, general terms and conditions of the awards, and significant assumptions used were some other areas where clarification was sought. In cases where the estimated stock price wasn't disclosed, the SEC has reserved the right to comment once the estimated price range is made known.

As a result new registrants should be mindful to disclose the nature and terms of awards, cost of capital used for issuances, its impact on the income statement, and the methods employed for estimating the fair value of grants in their draft registration statement.

SAMPLE COMMENTS

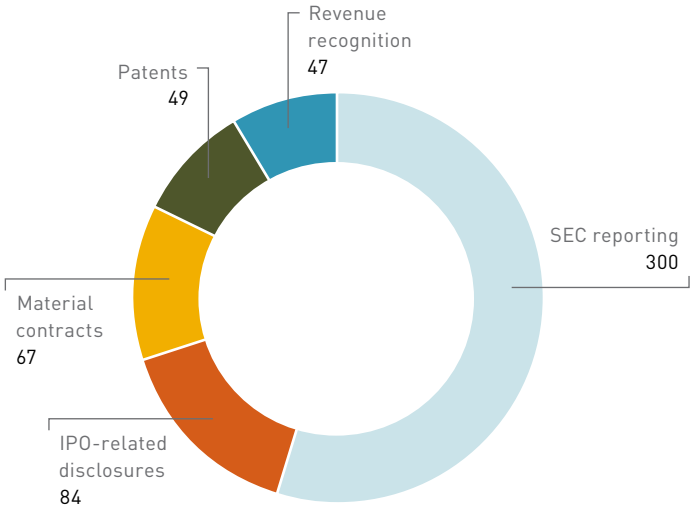
- Please revise your disclosures to address the following items related to your stock option grant valuation methodology:
  - The assumptions that led you to the conclusion that the same underlying stock price could be utilized from the date of the independent third-party valuation and each respective grant date

- Your rationale for switching the valuation methodology for the underlying common stock value from the option pricing method to the probability-weighted expected return method beginning on the [date] to [date] grant period
- The reason for the per-share estimated fair value of common stock remaining at [price] for each grant period when there appear to be significant changes in assumptions throughout the grant periods, including the conversion from the option pricing method to the probability-weighted expected return method and the decline in the discount for lack of marketability from [percent] to [percent] throughout the grant periods

- We have reviewed your stock-based compensation disclosures and have the following comments:
  - We note that you used an assumed cost of capital of [percentage range] at each valuation date. Please disclose the source used to determine the assumed cost of capital at each period.
  - We may have additional comments on your accounting for stock compensation and related disclosure once you have disclosed an estimated offering price. Please provide quantitative and qualitative disclosures explaining the difference between the estimated offering price and the fair value of each equity.
- Please provide the following information separately for each equity instrument issuance through the date of your response:
  - The date of the transaction
  - The number of equity instruments granted or shares issued
  - The exercise price of equity instruments granted, if any
  - Management's estimated fair market value per share and how the estimate was developed; please disclose the judgments made regarding future trends and factors and indicate whether the valuation was contemporaneous or retrospective
  - The identity of the recipient, indicating if the recipient was a related party
  - The nature and terms of concurrent transactions
  - The amount of any compensation or interest expense element

Other Disclosure Topics

NUMBER OF COMMENTS BY OTHER CATEGORIES



Other disclosure topics in SEC comments to S-1 filings included SEC reporting, IPO-related disclosures, material contracts, patents, and revenue recognition. Of these, comments related to SEC reporting made up more than 50 percent of the total.

Material Contracts

Recent comment letters have directed registrants to file agreements (especially true for lockup agreements) as an exhibit in accordance with Item 601 of Regulation S-K. The SEC has further sought disclosures on the material terms of the contracts, including the rights and obligations of the parties, aggregate amounts paid or received under the agreement, aggregate potential milestone payments, royalty rates, duration, and termination provisions.

SAMPLE COMMENTS

- In your discussion of each of the agreements, please clarify the term of the agreement by specifying the minimum number of years following the first commercial sale after which the royalty term for a given product expires. We note that you have requested confidential treatment for this information in the agreements cited. However, the duration of an agreement represents material information necessary for an investor's understanding of the agreement's terms and obligations. Because the duration of the royalty obligation is directly related to the term of these agreements, we would also view this as material information that must be disclosed in the registration statement. Please revise your disclosure accordingly.
- With respect to your collaborative research agreement with [company name] for the biological evaluation of selecting antagonists, please disclose all the material terms agreed to by the parties. This includes:
  - > Material payment terms, including royalties owed
  - > Scope of the research activities and allocation of responsibilities
  - > The relevant intellectual property covered and rights conveyed as to such property
  - > The duration of the agreement
  - > The material termination provisions

SEC Reporting

When filing draft registration statements, registrants must ensure that the information being submitted is accurate, complete, and complies with the instructions and format prescribed in Regulation S-K. Comments in this section are primarily related to the filing of exhibits and other material, submission of written communications to potential investors, requests for confidential treatments, demand for updated disclosures and clarifications, and the inclusion of relevant persons' signatures.

SAMPLE COMMENTS

- Please provide us with any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. Similarly, please provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.
- Please amend your registration statement to provide the power of attorney that allows your CEO to sign on behalf of your directors and officers. You may either file the power of attorney as an exhibit to the registration statement or include it on the signature page.
- We note that the company's Form 8-K is currently under review by the staff. Please note that we will not be in a position to accelerate the effectiveness of your registration statement until such review is complete and any comments are resolved. Additionally, please ensure that you update disclosures in the Form S-1 to conform to any changes made in the progress of our review of your pending Form 8-K.

IPO-Related Disclosures

Item 504 of Regulation S-K instructs registrants to describe the amounts and purposes for which the net proceeds from the sale of securities will be used. Over 40 percent of the comments in this category came from the use of proceeds. The SEC asked for disclosures on the amount to be used for each purpose to be listed in the draft statement. Other comments related to the actual offering itself, with clarifications required on the proposed maximum aggregate offering price and total number of units and common stock being offered.

SAMPLE COMMENTS

- We note that you are planning to:
  - > Initiate the [product name] and [product name] trials and then submit an NDA for [product name] for the treatment of chorea in Huntington's patients to the FDA in the fourth quarter of 2014
  - > Seek regulatory approval for [product name] in foreign jurisdictions
  - > Initiate a Phase 2/3 efficacy clinical trial of [product name] for the treatment of tardive dyskinesia
  - > Initiate a Phase 1b clinical trial of [product name] for the treatment of tics associated with Tourette's syndrome

  Please amend your disclosure to include the estimated amount of proceeds you plan to allocate for each of these uses and expand your disclosure to identify the stage of each trial or regulatory process that you expect to reach using the allocated proceeds. Additionally, please disclose whether you expect the proceeds will be used for clinical studies.
- After your IPO price range has been set, disclose each significant factor contributing to the difference between the fair value as of the date of each grant of equity instrument issued, including options, any warrants classified as equity instruments, and preferred stock, and the estimated IPO price or when a contemporaneous valuation by an unrelated valuation specialist was obtained subsequent to the grants but prior to the IPO. Reconcile and explain the differences between the midpoint of your estimated offering price range and the fair values included in your analysis. Please ensure that all of your equity instruments issued during the periods presented are included in your tabular disclosure. Revise your tabular disclosure as necessary to include information for all equity instruments issued subsequent to the balance sheet date through the date of your latest response.
- Please revise your disclosure throughout your registration statement to clarify whether you applied to obtain listing of your common stock and, if so, the status of your application. If you have not yet filed an application, please expand your disclosure to clearly state that an application has not yet been filed and disclose when you expect to file such an application.

Revenue Recognition

A majority of the comments in the revenue recognition category related to multiple element agreements—primarily the nature of the agreement, methods to determine the selling price of deliverables, the stand-alone value of delivered items, and the accounting period involved.

Other areas that attracted comments included revenue recognition policy, milestone method of revenue recognition, reduction in revenue, and deferred revenue. The SEC has also sought clarification on potential payments, royalty provisions, refunds, and services performed for certain collaborative arrangements.

SAMPLE COMMENTS

- You disclose your criteria of identifying a milestone as being substantive. Please tell us how each of these criteria are consistent with the guidance in ASC 605-28-25-2. In your response specifically tell us:
  - How your policy considers the requirement in ASC 605-28-25-2a that the achievement of the milestone is a direct result of your performance or an enhancement of value resulting from a specific outcome based on your performance. In this regard, as it applies to your agreement with [company name], it appears that [product name's] performance will result in the achievement of the various milestones.
  - How your policy considers the requirement in ASC 605-28-25-2b that the achievement of the milestone relates solely to past performance.
  - Why a reasonable amount of time must pass as indicated in your fifth criterion to qualify as a substantive milestone.
- You disclose that on [date], simultaneous with entering into the Amended License and Supply Agreement, the company and [company name] entered into a purchase agreement, pursuant to which [company name] purchased [number] of the company's common shares for an aggregate purchase price of [dollar amount]. You also state on [page number] that on [date], [company name] announced that the company had extended [company name's] exclusive territory in return for selling its equity ownership of [company name] for [dollar amount]. As these transactions appear to be done simultaneously, it appears you should consider all of them together when determining how to record the revenue. Please revise to clarify the accounting treatment. Refer to ASC 605-25-3. Provide the required disclosures under ASC 605-25-50. If you believe any of the deliverables have stand-alone value, please clarify the basis for your conclusions.
- You disclose that you have been awarded reimbursement contracts and development grant contracts. Please tell us whether any of these contracts contain repayment, refund, or royalty provisions depending upon the outcome or the underlying activities. If so, please tell us why it is appropriate to recognize revenue when you incur the costs and reference for us the authoritative literature you rely upon to support your accounting. Please revise your disclosure accordingly.

Patents

Patents are vital to the life sciences industry and particularly to companies in the pharmaceutical preparations space. Our analysis shows that nearly 70 percent of the SEC's comments related to patents were from the pharmaceutical preparations industry. The SEC has regularly asked for disclosures on the duration, geographical coverage and jurisdictions, pending applications, challenges and infringements, protection, and ownership of registrants' material patents.

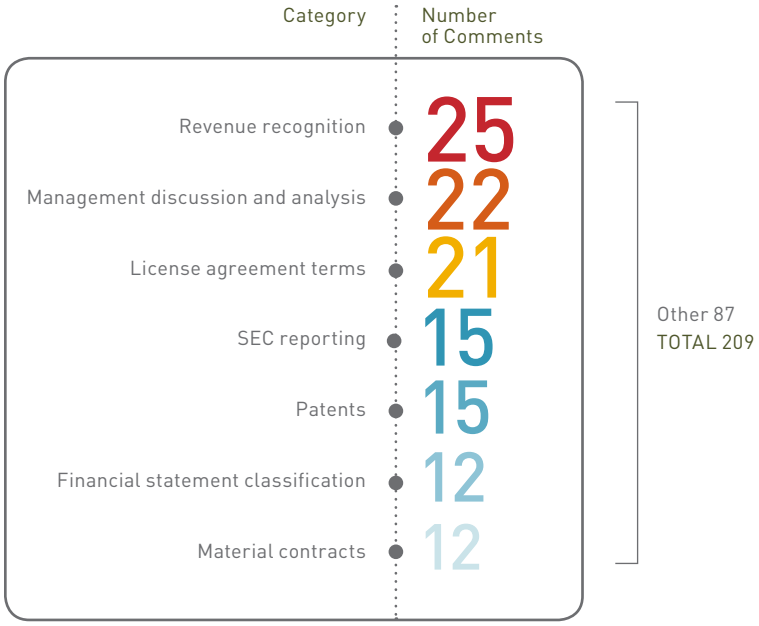
SAMPLE COMMENTS

- For the intellectual property covering [product names], please disclose:
  - > The exact number of issued US patents and pending US patent claims
  - > The specific type of patent protection relating to each issued or pending patent
  - > The expiration date of each of the identified material patents and the expected expiration date of each of the identified material patent applications
  - > Whether each issued or pending patent is owned by or licensed to the company
- As to any licensed material intellectual property related to your product candidates or proprietary technology, indicate from whom such property was licensed and describe the material terms of the license agreement and the duration of the license, including any conditions that must be satisfied in order to maintain the license. Please file all such license agreements as exhibits to your registration statement. Alternatively, provide us with your analysis as to why you are not substantially dependent upon any such licenses.
- We note that you have patents and patent applications abroad that relate to your US patent portfolio. Please identify any patents that cover material non-US jurisdictions and provide the jurisdictions, expiration dates, and other relevant information comparable to your disclosures regarding your US patent portfolio.

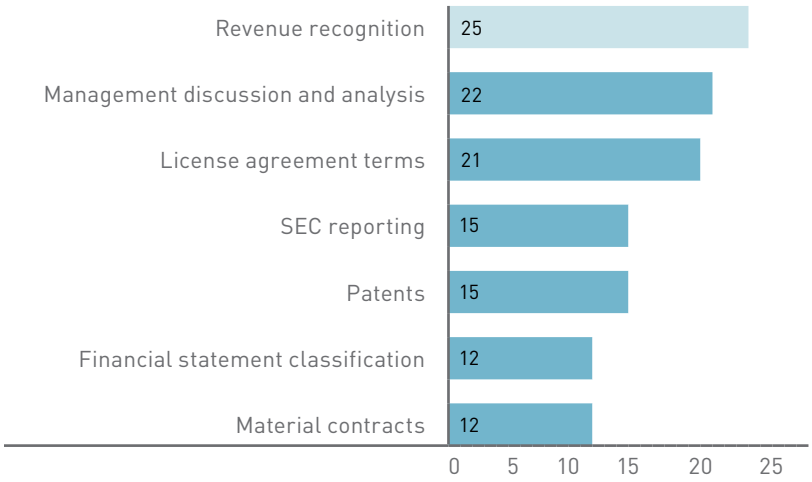
Trends in 10-K, 10-Q, and 20-F Reports

Comments directed toward post-IPO companies accounted for a minority of those analyzed in our study. Over the period of our review, only one in 10 comments was directed toward a 10-K, 10-Q, or 20-F report. Comments related to revenue recognition, MD&A, and terms of license agreements all proved to be trending topics for post-IPO companies.

OVERVIEW OF SEC COMMENT CATEGORIES FOR 10-K, 10-Q, AND 20-F REPORTS

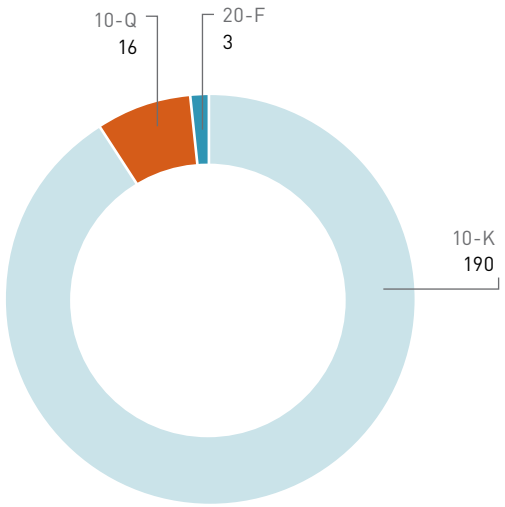


KEY AREAS OF FOCUS BY THE SEC FOR 10-K, 10-Q, AND 20-F FILINGS BY FREQUENCY OF COMMENTS



The vast majority of comments were directed toward 10-K reports, with only 9 percent directed toward 10-Q or 20-F reports.

BREAKDOWN OF 10-K, 10-Q, AND 20-F COMMENTS BY REPORT TYPE



While the smaller sample size of comments toward post-IPO companies (209) as opposed to pre-IPO companies (1,840) makes it difficult to truly compare trends, it's reasonably clear that the SEC has placed a greater emphasis on specific topics in the post-IPO filings.

While comments related to revenue recognition policies, for example, accounted for 12 percent of post-IPO comments (and was the most frequent category for comment), they accounted for just 3 percent of comments on S-1 filings. This reflects the increase in materiality of revenue recognition policies as a result of increased revenue (and thus the greater importance to shareholders) for companies that have transitioned from an early-growth stage to a middle-market stage. Other topics of greater relative focus from the SEC included MD&A, patent-related disclosures, terms of license agreements, and financial statement classification.

Conversely, several topics that featured prominently for S-1 filings attracted less focus for post-IPO filings. Disclosures on entity-related information, for example—one of the most significant trending topics for S-1 reports—attracted a negligible number of comments for post-IPO reports. This may reflect a higher capacity on the part of middle-market businesses to comply with SEC standards and guidelines, perhaps the result of more experience in filing SEC forms and access to resources. Other topics of lesser relative focus from the SEC included disclosures on risks, R&D, and share-based compensation.

Areas of Focus

Revenue Recognition

The SEC continues to focus on a company's accounting treatment for revenue recognition in accordance with ASC 605, Revenue Recognition. Multiple element arrangements and the revenue recognition policies for these were the SEC's primary target, with comments essentially asking for greater disclosures on the nature of the arrangements, key deliverables, and factors or assumptions used to derive prices.

SAMPLE COMMENTS

- You state, "We recognize promotion services revenues as a percentage of our collaborators' product sales revenue for these exclusively promoted products." Please provide us an analysis of how you determine the price to use to recognize revenue at delivery and how that price is fixed or determinable at that date. Also, provide proposed disclosure to be included in future periodic reports that states how you account for the cost of this revenue.
- Please refer to your revenue recognition policy for [product name's] molecular test systems.
  - > Tell us:
    - The delivery period and how you recognize revenue for each of the elements in the bundled product that includes an instrument, instrument accessories, and test kits
    - What the sentence "If not sold outright, amounts invoiced for the [product name] test kits cover the instrument, accessories, and test kits" means, particularly with regard to "if not sold outright" and the use of "test kits" twice in that sentence
    - How you recognize revenue in cases when "not sold outright"
    - How your revenue recognition policy that says "Revenue is recognized based on test kit sales" works and how it complies with GAAP assuming "test kit" refers to that which is included in the bundled product (i.e., the [product name] molecular test system)
    - Why it is appropriate under GAAP to recognize, if not sold outright, costs for the instruments over their three-year expected utilization period and how you recognized the costs of the other elements of the bundled product (i.e., instrument accessories and test kits)
  - > Provide us proposed revised revenue recognition policy disclosure to be included in future periodic reports to address the above bullets, as necessary, and to otherwise clarify your policy.

Management Discussion and Analysis

MD&A has consistently been one of the areas of greatest scrutiny by the SEC, and this trend continued in our findings for post-IPO filings. The MD&A comments in our analysis were focused on results from operations, though a significant portion also addressed liquidity and capital resources.

Major topics within results from operations included product sales and prices changes, allocation of revenue toward third-party agreements, and cost of goods sold. Topics within liquidity and capital resources included cash flow and accounts receivable and pension liabilities.

SAMPLE COMMENTS

- You state that "the retail list price of [product name] was reduced by approximately [percent figure]. The reduction was announced in [month and year] and became effective on [date]. Based on an agreement with our primary importer of [product name] into China, this importer will take a larger share of the price reduction impact in exchange for certain exclusive importation rights into China. As a result, the actual impact on [company name's] revenue and margins is expected to be less than a [percent figure] decrease in our sales price of [dollar figure] to this importer." Since you state the price reduction was effective on [date], please update this disclosure by providing us proposed disclosure to be included in future periodic reports stating the actual impact of the price reduction. In addition, include in the proposed disclosure the impact of this list price reduction on your sales related to your other importers.
- You state that "the cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of [product name] API as well as a portion of API carried at zero cost for material which was purchased prior to FDA approval of [product name] on [date]." Please provide us proposed disclosure to be included in future periodic filings addressing the following:
  - > Quantify the impact this zero-cost inventory had on your historical results of operations, including cost of goods sold and gross margin percentages, for each period and/or year presented.
  - > Quantify the estimated selling value of zero-cost inventory on hand as of the latest period presented and indicate its remaining shelf life.
  - > Estimate, based on your current sales trends, the time period when the zero-cost inventory will be depleted.
- Based on the disclosure on [page number], your domestic pension plans appear to be significantly unfunded. You state that the company's qualified pension plans are adequately funded at [date] and that you do not expect to significantly fund your qualified pension plans in [fiscal year] in order to meet minimum statutory funding requirements. You state that you expect to contribute [dollar amount] to domestic nonqualified pension plans and other postretirement plans. In light of the significant benefit payments that are due over the next five years as outlined in the table on [page number], please provide proposed disclosure to be included in future filings to address the following:
  - > Clearly state how you intend to fund your domestic pension obligations.

- Clarify what you mean by "adequately funded" with respect to your qualified pension plans, given that it appears the plan is significantly underfunded.
- Clarify why no minimum funding is required for your qualified pension plan, despite the apparent underfunded status.
- Clarify why the unfunded pension obligation has increased significantly over the last two years.
- Clarify how you have reflected your pension obligations in the contractual obligation table on [page number] or revise the table accordingly.

License Agreement Terms

Life sciences companies often maintain license agreements for technology, products, patents, branding, among other things. The terms of these agreements directly affect their value—and thus have a material impact on a company's operations and financial position. As a result, the SEC's comments have included asking registrants to expand their disclosures on license agreements, including the nature of goods or intellectual property transferred, parties' rights and obligations, up-front payments, aggregate milestone payments, royalty rates, and termination provisions.

SAMPLE COMMENTS

- Please disclose the material terms of your license agreements with [company name] and your agreements with the National Institutes of Health. Your description should include, as applicable:
  - The nature of the licensed technology and of the license
  - Material payment provisions including initial, annual, milestone, or royalty payments
  - Other material rights and obligations of both parties
  - Term and termination provisions

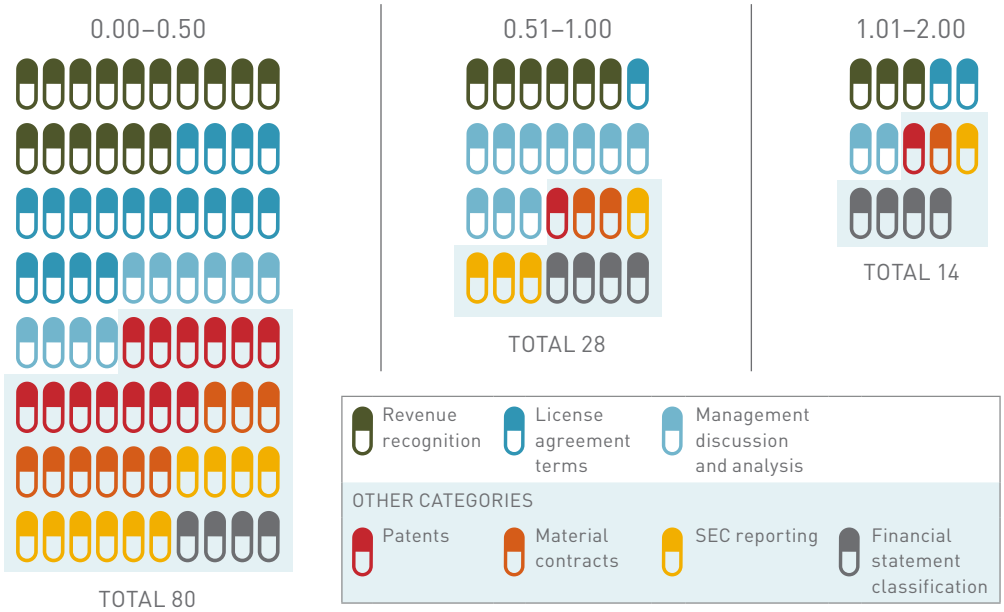
  Please also file the [company name] agreements as exhibits to your next quarterly report on Form 10-Q and incorporate them by reference to your next 10-K.
- Please revise your disclosure to include a discussion of the material terms of your collaboration and license agreements, as follows:
  - For your license agreement with [company name], [company name], and [company name]:
    - Percentage range of royalties (within a 10 percent range, e.g., "10–20%," "single digits")
    - Termination provisions
  - For your sublicense agreement with [company name]:
    - Aggregate milestone payments
    - Percentage range of royalties
    - Termination provisions

> For your collaboration agreement with [company name]:
  - Percentage range of royalties
  - Termination provisions

Market Capitalization Ranges

For post-IPO filings, the vast majority of comments in the major focus areas (barring "other comments") were directed toward companies with market capitalizations on the lower end of our target range (up to $2 billion). Sixty-five percent of comments were directed toward companies with market capitalizations of less than $500 million, and 88 percent were directed toward those in the lower 50th percentile, with only 14 comments directed those whose market capitalizations were greater than $1 billion.

TRENDS IN SEC COMMENT CATEGORIES
BY MARKET CAPITALIZATION (IN BILLIONS OF DOLLARS)



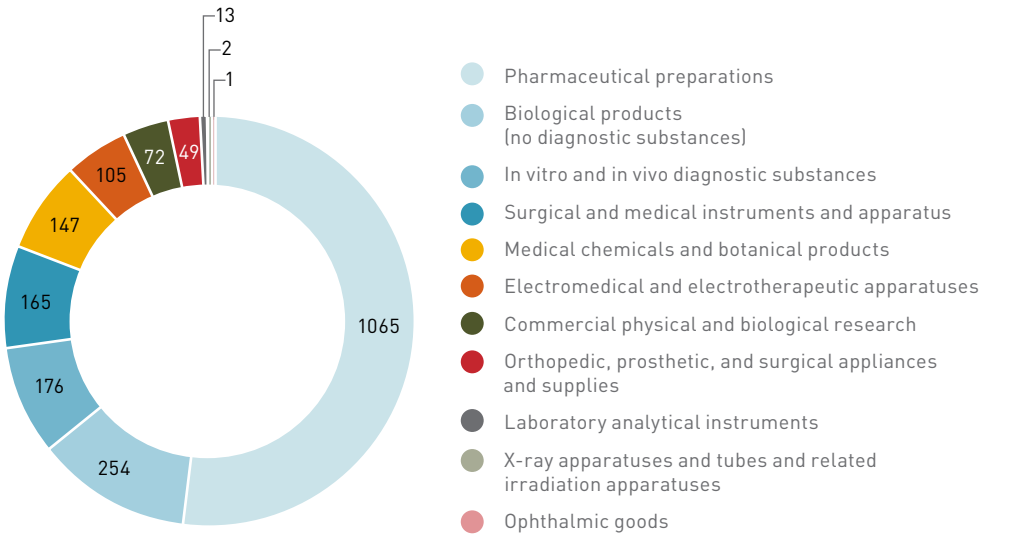
These results indicate that the norm is for less operationally mature companies to face the brunt of SEC scrutiny on their filings (which is confirmed by the SEC's considerable focus on S-1 filings). Specifically, the SEC has placed a relatively stronger focus on license- and patent-related disclosures from smaller-cap companies.

It's likely that the number of comments issued by the SEC and a company's market capitalization are negatively correlated because companies with higher market capitalization have greater access to resources, operational experience, and time to set up more effective compliance frameworks. For less operationally mature companies to reach this stage, it's important to carefully consider the level of disclosure expected and to ensure that investors are fully apprised in this context.

Subindustry Trends

Of the 12 subindustries included in our analysis, pharmaceutical preparations received the largest number of comments (over 50 percent). This stands to reason, since the majority of S-1, 10-K, 10-Q, and 20-F filings during the period under our analysis were from companies in the pharmaceutical preparations subindustry, which, after all, covers a broad set of companies—those, according to the government's definition, that are primarily engaged in "manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use," including "ampoules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions."

NUMBER OF COMMENTS BY SUBINDUSTRY



While each of the above subindustries technically operates in the life sciences industry, they individually could be subject to varied regulatory and market environments. It follows that companies in these subindustries could individually have vastly different business models, which ultimately can result in different areas of focus for the SEC. Given this, what trends an we identify?

First, there appears to be a significantly greater focus on disclosures of risks relating to companies in the medical chemicals and botanical products subindustry. In fact, 31 percent of all comments directed toward this subindustry related to disclosures about risk, which was relatively higher than the remaining subindustries.

Second, there was a marginally greater focus on disclosures relating to revenue recognition from companies in the commercial physical and biological research subindustry. Ten percent of all comments directed toward this subindustry related to revenue recognition, compared with the low-to-mid single digits for most other subindustries. This could well be a consequence of the greater complexity in revenue-related accounting for service providers as well as inherent challenges in pricing research services.

Finally, the SEC has placed significantly greater emphasis on R&D disclosures from companies in the pharmaceutical preparations subindustry. Indeed, 75 percent of all comments related to R&D were directed toward companies in pharmaceutical preparations, despite the fact that these comments amounted to only 51 percent of all comments across all categories. The results reflect the extraordinary amount of R&D-related expenses incurred by companies in the pharmaceutical field compared with those of other life sciences subindustries.

Conclusion

As we can see from the sample comments throughout this report, the SEC is asking life sciences companies for a wide range of very specific clarifications to their draft statements. Whether they involve further explanations of adverse side effects of medications, more detailed disclosures for license agreements, or more granular information regarding revenue recognition, the comments are forcing companies to work harder to meet the bar set by the SEC.

What can we take away from this?

First, the SEC is asking for, in many cases, very complex disclosures that many middle-market and pre-IPO companies may not have had to provide in the past and may be unfamiliar with as they go through this process for the first time. What's more, the process is getting more complex, not less, making the need to understand what the SEC is looking for that much greater.

Second, getting the process right (or mostly right) the first time around is less expensive and resource-intensive than facing the prospect of a raft of SEC comments that force you to amend your draft statement in many different places. In addition to the internal frustration this can engender, it risks delaying your IPO and sapping investor confidence.

As a result, learning from others that have come before you is critical. Preparing your statements in a manner that anticipates SEC comments—and proactively addresses them—can only help you speed the process and smooth the way for a successful outcome.

It's also important to work with advisors familiar with the SEC's approach to life sciences companies and who can guide your business through the compliance thicket. Industry-specific experience is key here, as is a deep understanding of the SEC's approach.

To gain more insight into the SEC's comment process or for help preparing your company for its IPO, contact a Moss Adams life sciences professional in your region:

Pacific Northwest

Findley Gillespie, Partner
(206) 302-6212
findley.gillespie@mossadams.com

Northern California

Richard Croghan, Partner
(415) 677-8282
richard.croghan@mossadams.com

Southern California

Carisa Wisniewski, Partner
(858) 627-1402
carisa.wisniewski@mossadams.com

All Other Locations

Eric Miles, National Practice Leader
(408) 916-0571
eric.miles@mossadams.com

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