

NOVARTIS AG  
Form 6-K  
June 01, 2011

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 or 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K dated June 1, 2011**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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Yes:  **No:**

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**Novartis International AG**

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**- Investor Relations Release -**

**Novartis highlights extensive data on numerous compounds at ASCO in multiple cancers, including Phase III studies in GIST and myelofibrosis**

- *Plenary presentation of Phase III study examining benefit of extended adjuvant treatment with Glivec® for three years vs. one year for patients with KIT+ GIST*
- *Two positive Phase III studies of INC424 (ruxolitinib) in myelofibrosis, a severely debilitating blood cancer with limited treatment options*
- *Sub-analysis from ENESTnd comparing Tasigna® to Glivec as first-line therapy in Ph+ CML-CP showing fewer mutations emerge with Tasigna than Glivec*
- *Data for novel PI3K inhibitor BEZ235 as well as TKI258 (dovitinib), LDE225 and LBH589 (panobinostat) showing strength and depth of pipeline*

**Basel, June 1, 2011** Novartis will showcase data from 140 abstracts on its current oncology products and investigational agents at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO). These data underscore the company's commitment to developing treatments to improve the lives of patients with cancer.

Through our commitment to R&D and collaborations with the scientific and patient communities, we continue to bring targeted treatments to patients living with cancer and other diseases for which there is an unmet need, said Hervé Hoppenot, President, Novartis Oncology. Our broad and deep portfolio of development programs gives us multiple opportunities to further advance treatments for the millions of patients and their families affected by these diseases.

Highlighted at the ASCO meeting, taking place from June 3 - 7 in Chicago, will be results from key Phase III studies on Novartis products and compounds, including a trial on adjuvant treatment with Glivec® (imatinib)\* in patients following resection of KIT (CD117)-positive gastrointestinal stromal tumors (GIST) featured at the plenary session on June 5, and two pivotal studies of the Janus kinase (JAK) inhibitor, INC424 (ruxolitinib), in patients with myelofibrosis on June 6(1). In addition, a study of patients with Philadelphia

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chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP), showing patients on Tasigna® (nilotinib) are less likely to develop mutations than those taking Glivec, will be presented on June 6(1).

Also featured at the Annual Congress will be results from two sub-analyses of the landmark Medical Research Council Myeloma IX clinical trial comparing the effect of Zometa® (zoledronic acid) Injection versus clodronate, on overall survival, progression-free survival and skeletal-related events when used with first-line chemotherapy in newly diagnosed multiple myeloma patients(1). Final results of the international Phase IV study, REACT (RAD001 Expanded Access Clinical Trial in RCC), evaluating Afinitor® (everolimus) tablets for the treatment of advanced renal

cell carcinoma following any available vascular endothelial growth factor targeted therapy, will also be presented(1).

Notable data about Novartis treatments at ASCO include:

- **Glivec** Two studies on Glivec in KIT+ GIST, including a Phase III trial examining the benefit of extended adjuvant treatment for three years versus one year with Glivec for patients following resection of their KIT+ GIST (ASCO abstract #LBA1; June 5, 1:45 - 2:00 PM CDT) and long-term follow up of the pivotal Phase II trial examining overall survival and progression-free rates in patients with metastatic and/or inoperable GIST treated for nearly 10 years with Glivec (ASCO abstract #10016; June 4, 8:00 AM - 1:00 PM CDT).
- **INC424** Data from two pivotal Phase III studies evaluating INC424 in patients with myelofibrosis after 48 weeks of treatment compared to best available therapy in the COMFORT-II trial (ASCO abstract #LBA6501; June 6, 9:45 - 10:00 AM CDT), and after 24 weeks of treatment compared to placebo in COMFORT-I (ASCO abstract #6500; June 6, 9:30 - 9:45 AM CDT).
- **Tasigna** Mutation analysis from ENESTnd comparing Tasigna to Glivec in patients with newly diagnosed Ph+ CML in chronic phase (ASCO abstract #6502; June 6, 10:00 - 10:15 AM CDT) and ENESTnd 24-month update (ASCO abstract #6511; June 3, 2:00 - 6:00 PM CDT).
- **Zometa** Two new Myeloma IX analyses evaluate the impact of treatment initiation and duration, and baseline bone disease status, on the effect of Zometa versus clodronate on progression-free survival, overall survival and skeletal-related events when used with first-line chemotherapy in patients with newly diagnosed multiple myeloma (ASCO abstract #8011; June 5, 11:00 - 11:15 AM CDT; ASCO abstract #8010; June 5, 10:45 - 11:00 AM CDT), as well as Austrian Breast & Colorectal Cancer Study Group Trial 12 (ABCSG-12) long-term follow-up data examining the impact of adjuvant Zometa therapy on disease-free survival and overall survival in premenopausal women with endocrine-responsive early breast cancer based on patient and tumor characteristics (ASCO abstract #520; June 7, 8:00 AM - 12:30 PM CDT).
- **Afinitor** Two Phase IV studies evaluating Afinitor treatment for advanced renal cell carcinoma following vascular endothelial growth factor targeted therapy (ASCO abstract #4601; June 5, 8:00 AM - 12:00 PM CDT; ASCO abstract #4552; June 7, 8:00 AM - 12:30 PM CDT), as well as data from three studies examining Afinitor as a treatment for certain patients with advanced neuroendocrine tumors, including two Phase III trials and one Phase I combination study with SOM230 (pasireotide) (ASCO abstract #4009; June 6, 2:00 - 6:00 PM CDT; ASCO abstract #4011; June 6, 2:00 - 6:00 PM CDT; ASCO abstract #4120; June 4, 8:00 AM - 12:00 PM CDT).
- **BEZ235** Phase I dose escalation study of PI3K inhibitor in patients with advanced solid tumors (ASCO abstract #3066; June 6, 8:00 AM - 12:00 PM CDT).
- **TKI258 (dovitinib)** Two Phase II studies examining dovitinib in FGFR1 amplified and non-amplified advanced breast cancer and in patients with advanced renal cell carcinoma (ASCO abstract #508; June 5, 10:30 - 10:45 AM CDT; ASCO abstract #4551; June 7, 8:00 AM - 12:30 PM CDT).

- **LDE225** An updated safety, preliminary efficacy and pharmacokinetic/ pharmacodynamic analysis from a Phase I study of the smoothed inhibitor in advanced solid tumors (ASCO abstract #3062; June 6, 8:00 AM - 12:00 PM CDT).

- **LBH589 (panobinostat)** An update of a Phase Ib study of oral panobinostat in combination with bortezomib in patients with relapsed or relapsed and refractory multiple myeloma (ASCO abstract #8075; June 6, 1:00 - 5:00 PM CDT) and a Phase III trial in progress of panobinostat plus bortezomib in relapsed/refractory multiple myeloma: PANORAMA-1, which is currently enrolling (ASCO abstract #TPS227; June 6, 8:00 AM - 12:00 PM CDT).

#### **About Glivec (imatinib)**

Glivec is approved in more than 110 countries, including the US, EU and Japan, for the treatment of all phases of Ph+ CML. Glivec is also approved in the US, EU and other countries for the treatment of patients with KIT (CD117)-positive gastrointestinal tumors (GIST), which cannot be surgically removed and/or have already spread to other parts of the body (metastasized). In the US and EU, Glivec is approved for the post-surgery treatment of adult patients following complete surgical removal of KIT (CD117)-positive gastrointestinal stromal tumors.

Not all indications are available in every country and indications may differ.

#### **Glivec Important Safety Information**

Glivec can cause fetal harm when administered to a pregnant woman. Women should not become pregnant, and should be advised of the potential risk to the unborn child.

Glivec is often associated with edema (swelling) and serious fluid retention. Studies have shown that edema (swelling) tended to occur more often among patients who are 65 and older or those taking higher doses of Glivec.

Cytopenias (reduction or lack of certain cell elements in blood circulation), such as anemia, have occurred. If the cytopenia is severe, your doctor may reduce your dose or temporarily stop your treatment with Glivec.

Severe congestive heart failure and left ventricle dysfunction have been reported, particularly in patients with other health issues and risk factors. Patients with heart disease or risk factors will be monitored and treated for the condition.

Severe liver problems (hepatotoxicity) may occur. Cases of fatal liver failure and severe liver injury requiring liver transplants have been reported with both short-term and long-term use of Glivec.

Bleeding may occur. Severe gastrointestinal (GI) bleeding has been reported in patients with Ph+ CML and KIT+ GIST. GI tumor sites may be the cause of this bleeding.

In patients with hypereosinophilic syndrome (a condition with increased eosinophils, which are a type of white blood cell), e.g., HES, MDS/MPD, or ASM and heart involvement, cases of heart disease (cardiogenic shock/left ventricular dysfunction) have been associated with the

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initiation of Glivec therapy. Skin reactions, such as fluid-filled blisters, have been reported with the use of Glivec.

Clinical cases of hypothyroidism (reduction in thyroid hormones) have been reported in patients taking levothyroxine replacement with Glivec.

Long-term use may result in potential liver, kidney, and/or heart toxicities; immune system suppression may also result from long-term use.

GI perforation (small holes or tears in the walls of the stomach or intestine), in some cases fatal, has been reported.



Growth retardation has been reported in children taking Glivec. The long-term effects of extended treatment with Glivec on growth in children are unknown.

Cases of tumor lysis syndrome (TLS), which refers to a metabolic and electrolyte disturbance caused by the breakdown of tumor cells, have been reported and can be life-threatening in some cases.

Almost all patients treated with Glivec experience side effects at some time. Some common side effects you may experience are fluid retention, muscle cramps or pain and bone pain, abdominal pain, loss of appetite, vomiting, diarrhea, decreased hemoglobin, abnormal bleeding, nausea, fatigue and rash.

Glivec is sometimes associated with stomach or intestinal irritation. Glivec should be taken with food and a large glass of water to minimize this problem. There have been rare reports, including deaths, of stomach or intestinal perforation (a small hole or tear).

If you are experiencing any of the mentioned side effects, please be sure to speak with your doctor immediately.

Do not take any other medications without talking to your doctor or pharmacist first, including Tylenol® (acetaminophen); herbal products (St. John's wort, Hypericum perforatum); Coumadin® (warfarin sodium); rifampin; erythromycin; metoprolol; ketoconazole; and Dilantin® (phenytoin). Taking these with Glivec may affect how they work, or affect how Glivec works.

You should also tell your doctor if you are taking or plan to take iron supplements. Patients should also avoid grapefruit juice and other foods that may affect how Glivec works.

#### **About INC424 (ruxolitinib)**

INC424 is an oral inhibitor, of the JAK1 and JAK2 tyrosine kinases. INC424 is being investigated in primary myelofibrosis as well as post-polycythemia vera (PV) myelofibrosis and post-essential thrombocythemia (ET) myelofibrosis. INC424 is also being investigated in clinical trials for the treatment of PV and secondary acute myelogenous leukemia.

Novartis licensed INC424 from Incyte for development and potential commercialization outside the US. Incyte has retained rights for the development and potential commercialization of INC424 in the US. Both the European Commission (EC) and the US Food and Drug Administration (FDA) have granted INC424 orphan drug status for myelofibrosis.

#### **About Tasigna (nilotinib)**

Tasigna® (nilotinib) 200 mg capsules is approved in more than 90 countries for the treatment of chronic phase and accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in adult patients resistant or intolerant to at least one prior

therapy, including Glivec. The effectiveness of Tasigna for this indication is based on hematologic and cytogenetic response rates.

Tasigna® (nilotinib) 150 mg capsules is also approved for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase. The effectiveness of Tasigna for this indication is based on major molecular response and cytogenetic response rates at 12 months. The study is ongoing and further data will be required to determine long-term outcome.

**Tasigna Important Safety Information**

Tasigna should be taken twice daily at an interval of approximately 12 hours apart and must not be taken with food. No food should be consumed for two hours before the dose and for at least one hour after the dose. Avoid grapefruit juice and other foods that are known to inhibit CYP3A4.

Tasigna should not be used in patients who are hypersensitive to nilotinib or any of the excipients.

Treatment with Tasigna has been associated with hematological side effects such as thrombocytopenia, neutropenia and anemia which was generally reversible and usually managed by withholding Tasigna temporarily or dose reduction. Complete blood counts should be performed every two weeks for the first two months and then monthly thereafter as clinically indicated.

Tasigna should be used with caution in patients with uncontrolled or significant cardiac disease (e.g., recent heart attack, congestive heart failure, unstable angina or clinically significant bradycardia), as well as in patients who have or may develop prolongation of QTc. These include patients with abnormally low potassium or magnesium levels, patients with congenital long QT syndrome, patients taking anti-arrhythmic medicines or other drugs that may lead to QT prolongation. Low levels of potassium or magnesium must be corrected prior to Tasigna administration. Close monitoring for an effect on the QTc interval is advisable and a baseline electrocardiography is recommended prior to initiating therapy with Tasigna and as clinically indicated. Uncommon cases (0.1 to 1%) of sudden death have been reported in clinical studies in patients with significant risk factors.

Tasigna should be used with caution in patients with liver impairment, in patients with a history of pancreatitis and in patients with total gastrectomy. Patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption should not use Tasigna. Tasigna should not be used during pregnancy unless clearly necessary and breast feeding is not recommended during treatment.

The most frequent Grade 3 or 4 adverse events for Tasigna were primarily hematological in nature and included neutropenia and thrombocytopenia. Elevations seen in bilirubin, liver function tests, lipase enzymes and blood sugar were mostly transient and resolved over time. These cases were easily managed and rarely led to discontinuation of treatment. Pancreatitis was reported in less than 1% of cases. The most frequent non-hematologic drug-related adverse events were rash, pruritus, nausea, fatigue, headache, alopecia, myalgia, constipation and diarrhea. Most of these adverse events were mild to moderate in severity.

#### **About BEZ235, TKI258 (dovitinib), LDE225 and LBH589 (panobinostat)**

Because these are investigational compounds, the safety and efficacy profile of BEZ235, TKI258, LDE225 and LBH589 have not yet been established. Access to these investigational compounds is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. Because of uncertainty of clinical trials, there is no guarantee that BEZ235, TKI258, LDE225 and LBH589 will ever be commercially available anywhere in the world.

#### **About Zometa (zoledronic acid)**

Zometa® (zoledronic acid) Injection is indicated for the prevention of skeletal-related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with multiple myeloma and advanced malignancies involving bone. Zometa, a potent third generation bisphosphonate, is the only bisphosphonate with demonstrated efficacy in reducing or delaying bone complications in multiple myeloma and across a broad range of tumor types such as breast, prostate, lung and renal cell cancers in patients with metastatic disease when administered monthly, as well as in the treatment of hypercalcemia of malignancy (HCM). Zometa is administered to patients as a 4 mg, 15-minute infusion.

#### **Zometa Important Safety Information**

Zometa has been associated with reports of renal insufficiency. Patients should be adequately rehydrated and have their serum creatinine assessed prior to receiving each dose of Zometa. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa

should not exceed 4 mg and the duration of infusion should be no less than 15 minutes in 100 ml of diluent.

The risk of renal adverse events may be greater in patients with renal insufficiency. Zometa is not recommended for treatment of patients with severe renal impairment. Severe and occasionally incapacitating bone, joint and/or muscle pain has been reported in patients taking bisphosphonates including Zometa. Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. Zometa contains the same active ingredient (zoledronic acid) as found in Aclasta. Patients being treated with Zometa should not be treated with Aclasta concomitantly. Zometa should not be used in patients who are pregnant, or plan to become pregnant, or who are breast-feeding.

In clinical trials, the most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Osteonecrosis of the Jaw (ONJ): ONJ has been reported in patients with cancer receiving treatment including bisphosphonates, chemotherapy and/or corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. No data are available to suggest whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures. A causal relationship between bisphosphonate use and ONJ has not been established.

#### **About Afinitor® (everolimus) tablets**

Afinitor® (everolimus) tablets is approved in the European Union (EU) for the treatment of patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy and also in the US for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib.

In Switzerland, everolimus is approved with the trade name Votubia® (everolimus) tablets for the treatment of patients 3 years of age and older with SEGA associated with tuberous sclerosis (TS) for whom surgery is not a suitable option. In the US, Afinitor is approved to treat patients with SEGA associated with tuberous sclerosis who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of everolimus is based on an analysis of change in SEGA volume. Clinical benefit such as improvement in disease-related symptoms or increase in overall survival has not been shown.

Afinitor is also approved in the US for the treatment of progressive neuroendocrine tumors of pancreatic origin in patients with unresectable, locally advanced or metastatic disease. The FDA determined that the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors have not been established.

In the EU, everolimus is available in different dosage strengths for the non-oncology patient population under the trade name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. In the US, everolimus is available in different dosage strengths under the trade name Zortress® for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant.

Everolimus is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Not all indications are available in every country. As an investigational compound the safety and efficacy profile of everolimus has not yet been established in all countries in pancreatic or any

other type of NET. Access to everolimus outside of the approved indications has been carefully controlled and monitored in clinical trials designed to better understand the potential benefits and risks of the compound. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for pancreatic or any other type of NET, or additional indications anywhere else in the world.

#### **Important Safety Information about Afinitor**

Afinitor can cause serious side effects including lung or breathing problems, infections, and renal failure which can lead to death. Mouth ulcers and mouth sores are common side effects. Afinitor can affect blood cell counts, kidney and liver function, blood sugar and cholesterol levels. Afinitor may cause fetal harm in pregnant women. Women taking Afinitor should not breast feed.

The most common adverse drug reactions (incidence  $\geq 15\%$ ) are mouth ulcers, rash, diarrhea, fatigue, acneiform dermatitis, infections, weakness, nausea, peripheral swelling, decreased appetite, headache, pneumonitis, abnormal taste, nose bleeds, mucosal inflammation, weight decreased and vomiting. The most common grade 3-4 adverse drug reactions (incidence  $\geq 2\%$ ) are mouth ulcers, fatigue, decreased white blood cell count, diarrhea, infections, pneumonitis and diabetes mellitus. Cases of hepatitis B reactivation and pulmonary embolism have been reported.

#### **About SOM230 (pasireotide)**

SOM230 is an investigational multireceptor targeting somatostatin analog (SSA) that binds to four of the five somatostatin receptor subtypes (sst 1, 2, 3 and 5).

Because it is an investigational compound, the tolerability and efficacy profile of SOM230 has not yet been fully established. Access to this investigational compound is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. There is no guarantee that SOM230 will become commercially available.

Information about Novartis clinical trials for SOM230 can be obtained by healthcare professionals at [www.paporttrials.com](http://www.paporttrials.com).

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as pipeline, will, commitment, potential, or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new products will be submitted or approved for sale in any market, or that any new indications will be submitted or approved for existing products in any market, or at any particular time, or that such products will achieve any particular revenue levels. In particular, management's expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed,

estimated or expected. Novartis is providing the information in this press release as of this date



and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

#### **About Novartis**

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>.

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#### **References**

(1) American Society of Clinical Oncology. ASCO Annual 11 Meeting Program. Available at: <http://chicago2011.asco.org/MeetingProgram.aspx>. Accessed May 2011.

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**SIGNATURES**

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

**Novartis AG**

Date: June 1, 2011

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
Title: Head Group Financial  
Reporting and Accounting