

NOVARTIS AG
Form 6-K
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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 December 2, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Form 20-F: Form 40-F:

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Yes: **No:**

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Novartis Global Communications

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- Investor Relations Release -

Significant potential of late- and mid-stage Novartis hematology portfolio to be showcased at upcoming ASH meeting

- *Late-breaking abstract to report data from pivotal trial of Tasigna® versus Glivec® in newly diagnosed patients with a form of chronic myeloid leukemia*
- *Data from Phase II studies to show the potential of everolimus in a rare form of non-Hodgkin lymphoma and of panobinostat in Hodgkin lymphoma^{1,2}*
- *Oral presentation featuring early data on midostaurin to show promise in FLT3-mutated acute myeloid leukemia³*
- *New data to be presented on a Janus kinase (JAK) inhibitor, recently added to the Novartis Oncology pipeline^{4,5}*
- *Two-year data from EPIC trial to demonstrate Exjade® continues to significantly reduce toxic iron that can damage the heart of chronically transfused patients⁶*

Basel, December 2, 2009 Novartis announced today that new data, including a late-breaking presentation on Tasigna® (nilotinib) in a form of chronic myeloid leukemia, demonstrate the strength of the company's hematology portfolio in advancing the care of patients.

The new data, at the 51st American Society of Hematology (ASH) Annual Meeting and Exposition, highlight the company's current therapies and investigational agents in 195 studies including 39 oral presentations. Data will be presented on Tasigna, Afinitor® (everolimus) tablets, Exjade® (deferasirox) and pipeline agents including PKC412 (midostaurin), LBH589 (panobinostat), BHQ880 and INCB18424, an oral, selective Janus kinase (JAK) inhibitor that was recently added to the oncology pipeline through a licensing agreement.

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Data presented at ASH will demonstrate the vigorous research underway to explore the best treatment approaches for patients with rare blood cancers and conditions, said David Epstein, President and CEO, Novartis Oncology and Novartis Molecular Diagnostics. We expect these data to lay the groundwork for regulatory submissions and provide a roadmap for the initiation of late-stage and pivotal trials.

The ASH Annual Meeting will feature results from a pivotal head-to-head study comparing the efficacy and safety of Tasigna versus Glivec® (imatinib)* in adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (Abstract #LBA-1; Tuesday, December 8, 2009 at 7:30 AM CST).

Data from this Phase III clinical trial, ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials of Newly Diagnosed Ph+ CML Patients), will show that Tasigna produced faster and deeper responses than Glivec when used as first-line therapy.

Other key presentations at ASH include:

- **Everolimus** Phase II data to show efficacy and safety in patients with Waldenström's macroglobulinemia (WM) who had relapsed or become resistant to prior treatment (Abstract #587; Monday, December 7, 2009 at 3:45 PM CST)¹
- **Panobinostat** data from two early phase studies to show efficacy in heavily pre-treated patients with multiple myeloma and Hodgkin lymphoma (Abstract #3852; Monday, December 7, 2009 at 6:00 PM CST; Abstract #923; Tuesday, December 8, 2009 at 8:30 AM CST)^{2,7}
- **Midostaurin** early stage data will demonstrate benefit in patients with FLT3-mutated acute myeloid leukemia when used in combination with chemotherapy (Abstract #634; Monday, December 7, 2009 at 5:15 PM CST)³
- **INCB18424** data from a Phase II study in advanced polycythemia vera (PV) and essential thrombocythemia (ET) refractory to hydroxyurea (Abstract #311; Monday, December 7, 2009, 8:00 AM CST)⁵
- **INCB18424** long-term follow-up data to demonstrate durable clinical, functional and symptomatic responses with excellent hematological safety in patients with myelofibrosis (Abstract #756; Monday, December 7, 2009 at 5:45 PM CST)⁴
- **Exjade** two-year data from EPIC (Evaluation of Patients Iron Chelation with Exjade) trial to show benefit of Exjade for chronically transfused beta-thalassemia patients by continuing to significantly reduce toxic iron that can damage the heart (Abstract #4062; Monday, December 7, 2009 at 6:00 PM CST)⁶
- **BHQ880** preliminary Phase I study data in combination with Zometa® (zoledronic acid) and an approved anti-myeloma therapy in patients with relapsed or refractory multiple myeloma who experienced a prior skeletal-related event (Abstract #750; Monday, December 7, 2009 at 5:45 PM CST)^{8,9}

The Novartis Oncology pipeline features compounds in all phases of development, including six in late-stage development, and encompasses a broad array of therapeutic strategies for fighting cancer.

About Tasigna¹⁰

Tasigna is approved in more than 80 countries for the treatment of chronic phase and accelerated phase 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 confirmed hematologic and unconfirmed cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

Tasigna important safety information

Because taking Tasigna with food may increase the amount of drug in the blood, Tasigna should not be taken with food and patients should wait at least two hours after a meal before taking Tasigna. In addition, no food should be consumed for at least one hour after the dose is taken.

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, constipation and diarrhea. Most of these adverse events were mild to moderate in severity.

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 echocardiogram is recommended prior to initiating therapy with Tasigna and as clinically indicated.

About Glivec11

Glivec is approved in more than 90 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 now approved for the post-surgery treatment of adult patients following complete surgical removal of Kit (CD117)-positive gastrointestinal stromal tumors. In the EU, Glivec is also approved for the treatment of adult patients with newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy and as a single agent for patients with relapsed or refractory Ph+ ALL. Glivec is also approved for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) who are not eligible for surgery. Glivec is also approved for the treatment of patients with myelodysplastic/myeloproliferative diseases (MDS/MPD). Glivec is also approved for hypereosinophilic syndrome and/or chronic eosinophilic leukemia (HES/CEL).

The effectiveness of Glivec is based on overall hematological and cytogenetic response rates and progression-free survival in CML, on hematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on hematological response rates in systemic mastocytosis (SM), HES/CEL, on objective response rates and progression-free survival in unresectable and/or metastatic GIST, on recurrence-free survival in adjuvant GIST and on objective response rates in DFSP. Increased survival in controlled trials has been demonstrated only in newly diagnosed chronic phase CML and GIST.

Not all indications are available in every country.

Glivec important safety information

The majority of patients treated with Glivec in clinical trials experienced adverse events at some time. Most events were of mild to moderate grade and treatment discontinuation was not necessary in the majority of cases.

The safety profile of Glivec was similar in all indications. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, abdominal pain, myalgia, arthralgia, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, dermatitis, eczema and fluid retention, as well as neutropenia, thrombocytopenia and anemia. Glivec was generally well tolerated in all of the studies that were performed, either as monotherapy or in combination with chemotherapy, with the exception of a transient liver toxicity in the form of transaminase elevation and hyperbilirubinemia observed when Glivec was combined with high dose chemotherapy.

Rare/serious adverse reactions include: sepsis, pneumonia, depression, convulsions, cardiac failure, thrombosis/embolism, ileus, pancreatitis, hepatic failure, exfoliative dermatitis, angioedema, Stevens-Johnson syndrome, renal failure, fluid retention, edema (including brain, eye, pericardium, abdomen and lung), hemorrhage (including brain, eye, kidney and gastrointestinal tract), diverticulitis, gastrointestinal perforation, tumor hemorrhage/necrosis and hip osteonecrosis/avascular necrosis.

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Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated. Cardiac screening should be considered in patients with HES/CEL, and patients with MDS/MPD with high level of eosinophils (echocardiogram, serum troponin level).

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

About everolimus

In the US, everolimus is approved under the trade name Afinitor for the treatment of patients with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib. In the European Union (EU), Afinitor is approved for the treatment of patients with advanced RCC whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. Further, in the EU, everolimus is available in different dosage strengths under the trade name Certican® for the prevention of organ rejection in heart and kidney transplant recipients.

With once-daily dosing, everolimus continuously targets mammalian target of rapamycin (mTOR) in cancer cells, a protein that acts as a central regulator of tumor cell division, blood vessel growth and cell metabolism. Everolimus is being studied in multiple tumor types, including breast cancer, neuroendocrine tumors, gastric cancer, hepatocellular carcinoma (HCC) and non-Hodgkin lymphoma (NHL), as well as tuberous sclerosis complex (TSC).

As an investigational compound, the safety and efficacy profile of everolimus has not yet been established in these cancer and tumor types. Access to everolimus for these cancer and tumor types is available through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. For more information about everolimus clinical trials, healthcare professionals can visit www.theWIDEprogram.com. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will ever become commercially available for these cancer and tumor types anywhere in the world.

Afinitor (everolimus) tablets important safety information

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients.

Cases of non-infectious pneumonitis have been described; some of these have been severe and occasionally fatal. Management of pneumonitis may require dose adjustment and/or interruption, or discontinuation of treatment and/or addition of corticosteroid therapy.

Afinitor is immunosuppressive. Localized and systemic bacterial, fungal, viral or protozoal infections (e.g., pneumonia, aspergillosis, candidiasis, hepatitis B reactivation) have been described; some of these have been severe and occasionally fatal. Pre-existing infections should be treated prior to starting treatment. Be vigilant for symptoms and signs of infection; in case of emergent infections, institute appropriate treatment promptly and consider interruption or discontinuation of Afinitor. Patients with systemic invasive fungal infections should not receive Afinitor.

Mouth ulcers, stomatitis and oral mucositis have been seen in patients treated with Afinitor. Monitoring of renal function, blood glucose and complete blood counts is recommended prior to initiation and periodically during treatment.

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Afinitor is not recommended in patients with severe hepatic impairment. Use of live vaccines should be avoided. Afinitor is not recommended during pregnancy or for women of childbearing potential not using contraception. Afinitor may cause fetal harm in pregnant women. Women should not breast feed.

Avoid concurrent treatment with strong CYP3A4 and PgP inhibitors and use caution with moderate inhibitors. Avoid concurrent treatment with strong CYP3A4 or PgP inducers.

The most common adverse reactions ($\geq 10\%$) include stomatitis, rash, fatigue, asthenia, diarrhea, anorexia, nausea, mucosal inflammation, vomiting, cough, infections, peripheral edema, dry skin, epistaxis, pneumonitis, pruritus, dyspnea and dysgeusia. Common adverse reactions (≥ 1 to $<10\%$) include headache, dry mouth, pyrexia, weight decreased, hand-foot syndrome, abdominal pain, erythema, insomnia, dyspepsia, dysphagia, hypertension, increased daytime urination, dehydration, chest pain, hemoptysis and exacerbation of diabetes mellitus. Uncommon adverse reactions ($<1\%$) include ageusia, congestive cardiac failure, new-onset diabetes mellitus, impaired wound healing, grade 1 hemorrhage and hepatitis B reactivation.

About Exjade

Exjade is approved in more than 90 countries, including the US, Switzerland, Japan and the countries comprising the European Union. Exjade is indicated for chronic iron overload due to blood transfusions. The approved indication may vary depending upon the individual country. Exjade is approved for use at doses up to 40 mg/kg in many countries, including the US, Canada, Australia, and Switzerland. Exjade may be available in additional countries at similar dosing pending approval. The European Medicines Agency (EMA) is currently considering an application for similar dosing (up to 40 mg/kg) in the European Union.

Disclaimer: The results seen in the EPIC study were achieved with a starting dose of 30 mg/kg, which is not approved in all countries and a dose range up to 45 mg/kg which is not approved in any country.

Exjade important safety information

Exjade is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. Exjade has not been studied in patients with renal impairment and is contraindicated in patients with moderate/severe renal impairment.

Caution should be utilized in high-risk MDS patients and patients with other hematological and non-hematological malignancies who are not expected to benefit from chelation therapy due to the rapid progression of their disease. Caution should be used in elderly patients due to a higher frequency of adverse reactions.

There have been postmarketing reports of acute renal failure, hepatic failure and cytopenias in patients treated with Exjade, some with a fatal outcome. Monthly monitoring of serum creatinine, creatinine clearance, proteinuria, serum transaminases is recommended, and the dose of Exjade should be modified or interrupted if necessary. More frequent creatinine monitoring is recommended in patients with an increased risk of renal complications. Liver function tests should be conducted every 2 weeks during the first month of treatment and monthly thereafter. Upper gastrointestinal ulceration and hemorrhage have been reported and caution should be exercised when combined with drugs with ulcerogenic potential. There have been rare reports of fatal GI hemorrhages, especially in elderly patients who had advanced hematologic malignancies and/or low platelet counts. Caution should be used in patients with platelet counts $<50 \times 10^9/L$. Skin rashes, including hypersensitivity reactions, have been reported. Exjade should be interrupted if severe rash develops and discontinued if severe hypersensitivity reaction occurs. Auditory and ophthalmic testing should be conducted annually.

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Exjade should not be taken with aluminium-containing antacids. Caution should be exercised when Exjade is combined with drugs metabolized through CYP3A4, CYP2C8 substrates, potent UGT inducers, drugs with ulcerogenic potential and anticoagulants.

The most common adverse reactions in clinical trials are nausea, vomiting, diarrhea, abdominal pain, rash, non-progressive increase in serum creatinine, increased transaminases, abdominal distension, constipation, dyspepsia, proteinuria and headache.

About midostaurin (PKC412)

Midostaurin is a multi-targeted kinase inhibitor that suppresses the FLT3 receptor tyrosine kinase, resulting in increased cell death and reduced cell division in tumors. The FLT3 gene is one of several cancer genes associated with the development of AML and approximately 30% of AML patients will have a mutation in their FLT3 gene. Patients who have this mutation have poor prognosis with reduced overall survival, and show higher relapse rates when compared to patients who do not have the mutation, often referred to as FLT3-wild-type.

There is an ongoing global randomized, placebo-controlled Phase III clinical trial called CALGB 10603-RATIFY (Randomized AML Trial In FLT3 in <60 Year Olds) to study midostaurin in combination with standard chemotherapy in newly diagnosed patients with FLT3-mutated AML. This is a multi-cooperative group global trial, sponsored by the Cancer and Leukemia Group B (CALGB) in North America and Novartis outside North America.

About panobinostat (LBH589)

Panobinostat is a potent pan-deacetylase (DAC) inhibitor. By interfering in the nucleus with gene expression and transcription, panobinostat decreases tumor cell division, causes tumor cell death and inhibits the formation of new blood vessels that feed tumors. Furthermore, in diseases that involve plasma cells such as multiple myeloma, panobinostat inhibits HDAC6 (a key enzyme in the elimination of pathologically hypersecreted monoclonal immunoglobulins) leading to cell death.

About BHQ880

BHQ880 is a first-in-class, fully human, anti-dickkopf-1 (DKK-1) neutralizing antibody. By inhibiting the DKK-1 antibody, BHQ880 promotes activity of osteoblasts, cells that form bones.

About INCB18424

INCB18424 (also known as INCB018424) is a Janus kinase (JAK) inhibitor. This oral targeted therapy is now in Phase III clinical trials for the treatment of myelofibrosis, a life-threatening neoplastic condition with no effective medical treatment that is characterized by varying degrees of bone marrow failure, splenomegaly (enlarged spleen) and debilitating symptoms. INCB18424 has the potential of becoming a first-in-class therapeutic agent for the treatment of this and other hematologic diseases.

About Zometa

Zometa is indicated for the treatment or prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with advanced malignancies involving bone. An intravenous bisphosphonate, Zometa is the only therapy to demonstrate efficacy in reducing or delaying bone complications across a broad range of tumor types such as breast, prostate, lung and renal cell cancers, in patients with metastatic disease when administered monthly. Zometa offers patients, nurses and clinicians a 4 mg, 15-minute infusion.

Zometa is the world's leading treatment for the prevention or delay of skeletal-related events (SREs) in patients with advanced malignancies involving bone across a broad range of tumors. Laboratory research has suggested that Zometa may also help protect patients from the spread of cancer to other parts of the body (distant metastatic sites) and help keep patients recurrence-free.

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.

Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. 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. 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.

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.

Not all indications are approved in every country. Please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, to present, to show, to demonstrate, can, will, to explore, pipeline, or similar expressions, or by express or implied discussions regarding potential new indications or labeling, or potential marketing approvals for the products described in this release, or regarding potential future revenues from 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 of the products or additional indications or labeling described in this release will be submitted for approval or approved for sale in any market. Nor can there be any guarantee that any of these products will achieve any particular levels of revenue in the future. In particular, management's expectations regarding these products 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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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: December 2, 2009

By: /s/ MALCOLM B. CHEETHAM

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