

As a company that Supports Oncology and Drug Development helping Pharmaceutical and Biotech Industries Complete their Clinical Trials while working with CROs, DAVA Oncology, LP. has been a part of Results that have Impacted the Advance of Cancer Research

**Biotechnology
Oncology**

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**Mark Levonyak
President**

BIO:

Mark Levonyak joined Dava Oncology as President in September 2007, bringing over twenty years of commercialization & business development expertise as a pharmaceutical and biotechnology executive. Mr. Levonyak has extensive global experience building commercial teams and launching new products in the hematology oncology marketplace.

DAVA Oncology develops and implements innovative medical and sci-

entific communication strategies and physician based accrual enhancement initiatives. During the last 4 years, Mr. Levonyak has successfully built DAVA Oncology into a profitable, boutique Oncology consulting company with year over year growth.

Previous to joining Dava Oncology, Mr. Levonyak spent two years at Anormed as the Executive Vice President, Global Sales & Marketing, where he developed the commercial strategy for a novel stem cell transplant mobilizer. Under his leadership Anormed became a coveted Canadian biotechnology company, that ultimately sold for half a billion dollars to Genzyme Corporation.

Prior to Anormed, Mr. Levonyak spent five years at CTI as the Vice President, Oncology & Hematology Marketing, where he lead the development of the sales, marketing and medical affairs organization and launched one of the most successful products in the leukemia marketplace.

The 15 years prior to joining CTI, Mr. Levonyak worked in numerous progressive commercial roles at Smith-Kline Beecham Pharmaceuticals. His final position was Oncology Commercial Director, where he developed and led the sales, marketing and medical affairs teams. Mr. Levonyak played a critical role in the creation of the SmithKline Beecham oncology business unit designed exclusively to compete in the oncology and hematology markets.

Mr. Levonyak earned his Bachelor degrees in both Biology and Chemis-

try from the California State University System.

About DAVA Oncology:

DAVA Oncology's mission is to facilitate successful drug development through innovative solutions and services that accelerate the patient enrollment process. DAVA maximizes the recruitment potential of each investigator participating in a given study through peer-to-peer interactions with our team of clinically experienced medical oncologists and oncology professionals.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Mr. Levonyak, Dava is facilitating successful drug development; would you explain what you are doing?

Mr. Levonyak: When you think of Dava Oncology, you think of a cancer research company but not in the same realm as a pharmaceutical company in that we do not have labs or molecules that we put into the patients to utilize. We help the pharmaceutical and biotech industries complete their clinical trials. We use our medical oncology team. We now have six medical oncologists on staff to work with their colleagues and their peers in a very one-to-one relationship to educate them about their patients and explore the opportunity, potentially putting patients on that clinical trial that we support. It is a very tactical approach. The other part of Dava Oncology is more strategic in nature where we actually help the

pharmaceutical and biotech companies with their plans for drug development.

CEO CFO: Are you benefiting from the trend toward outsourcing?

Mr. Levonyak: We thought initially five years ago when we started the company that we would work more with the smaller biotech companies. Five years later our work now encompasses projects (80%) with the Big Pharma. Large Pharmaceutical companies outsource their clinical trials to what is called a CRO. We work in support with that CRO to accelerate accrual to clinical trials.

CEO CFO: Would you explain the business model for us?

Mr. Levonyak: The companies that hire us are really the pharmaceutical industry and the biotech industry. We usually work along the side with the CRO if the CRO is chosen by the pharmaceutical company as an outsource operational vendor.

We are complimentary. We partner with the CRO but we typically contract directly with the pharmaceutical industry. If you look at patient recruitment companies, which are about two-thirds of what we do, the other third is strategy. There are many types of patient recruitment companies that go to the patient, do a great amount of advertising, and they try to get the attention of the patient. Our approach is completely different in that we do not go to the patients at all; we go to the investigators because cancer is so complicated, it is such a devastating diagnosis that when you have that diagnosis you put a ton of trust in the relationship with your medical oncologist. What we try to do is make sure that medical oncologist is as up to date on the clinical research, on the different trials that they have available for their patients, and we do that with that peer-to-peer relationship with our medical oncology team. If you categorize this, we would be a patient recruitment company with a completely different approach in that it is MD focused and not really focused on the patient end.

CEO CFO: Is big pharma well aware of DAVA and the difference you offer?

Mr. Levonyak: I think in any business it is all about exposure, marketing, and sales. After five years, DAVA Oncology is recognized as a patient recruitment company in the operational world of pharmaceutical companies and then recognized as a strategic thinker or knowledge-based companies in the commercial world. I think we have two entities. In fact, next year we are branching out and splitting the company into just DAVA Oncology for clinical trial support or doing a DBA, which states ONE oncology as our strategic arm. We do not want confuse our customers of what we do because I think we try to do everything under DAVA and now we are starting to actually segment out the companies. Awareness is good from the standpoint that we have many relationships, everybody here has had twenty plus years in the

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industry and we know many people but it can always be better. I do not think we are a household name, let's put it that way.

CEO CFO: What is new in oncology?

Mr. Levonyak: We just came out of one of the big meetings of the year called ESMO (European Society of Medical Oncology) which was in Vienna Austria just this last week. There are a many drugs currently in development, more than have ever been developed in the past. In fact, this year alone we have seen almost ten different oncology approvals if not more. There is a ton of activity, over 31% of the healthcare drug development dollars are spent in the oncology space and the trend is towards personalized medicine. The trend is towards finding the mutation in patients' bodies that will predict or develop a drug that will potentially work for those patients. Instead of the one-size-fits-all, everybody gets the same type of chemo, you now look for a biomarker, you look for a certain mu-

tation and companies are getting smarter to develop drugs that will actually target that mutation or that translocation.

CEO CFO: When a company comes to you for advice, how do you lead them?

Mr. Levonyak: There are two parts of the business. The knowledge and science piece are coming to us with a problem related to not understanding a certain pathway or not understanding a certain tumor type, or they may be relatively educated but they really need to take a deep dive. We have a team of PhD and we go deep into the data and tell them what the competitive threats are for their potential molecules, what would be the best route for development, if indeed we had the molecule. We give them advice and that is almost like a consulting role. They will come to us with a need because they do not understand something or they need to understand it a

little more and we helped them get there. On the clinical trials side, they typically come to us because they cannot find the right sites to open the trial, the sites are

not opening fast enough, or the sites that are opening are not accruing patients and that is where we implement our strategies and tactics. In order to help them open quicker, sometimes we have to find brand-new sites to participate and then the real essence of what we do is called physician focused patient recruitment, which is the one-on-one interaction with the medical teams at the sites. That can be done via phone calls or visits; we do a great deal of accrual workshops, so there are many different tactics that we use in order to accelerate the accrual of clinical trials.

CEO CFO: From what you said, you have very knowledgeable and qualified people in the field of oncology. How do you find and attractive exceptional employees?

Mr. Levonyak: One of the advantages we have was one of the reasons why we liked the two businesses together, which was that in order to understand the clinical trials of today, you have to understand how we got

there in the past and then look where we are headed in the future. The science or knowledge part of the business is up-to-date on the majority of what is happening in oncology. We go to all the major conferences. There are two big conferences, ASCO (American Society of Clinical Oncology) which focuses mostly on solid tumors, and then there is one coming up in December called ASH (American Society of Hematology), which is focused mostly on liquid tumors. We also go to the European programs; we go to the European Hematology Association and ESMO. We send PhD to go onsite, listen to the presentations, interpret the presentations, and then we sit with our medical teams and we give our opinions of the data. We are connected to what is happening; we are constantly doing literature searches. One of the new pieces of our business will be a curate system on our website. When you need to find information quickly, we are actually going to curate it for you so that you can access the information into your own research ad at one site versus going multiple sites. I feel as though with a company of 45 individuals, we do a very good job keeping ourselves focused and we do not do anything but oncology. Many of our competitors in the knowledge business will do oncology, rheumatology or dermatology. We do not do anything but cancer. We are very deep and we go as far as we possibly can base on the literature that is available.

CEOCFO: How does the company deal with the frustration of working with development that has potential to do so much good and yet is such an arduous process to get through?

Mr. Levonyak: It is difficult. The last article that I read was over a billion dollars to develop a drug, particularly in the hematology/oncology arena where it takes anywhere from eight to twelve years. There were many steps along the way and I think the most frustrating step was just what happened this last week, a trial that we helped support that was in lung cancer. We accrued very quickly and unfortunately, the trial was negative. That is drug development, we just have to be realistic and not give up hope that many of these drugs are going to be developed and many of them will be successful but that is a very small number when you look at the number that are currently in development. It is an arduous process, but it is a very safe process here in the US, we trust the FDA and think they make the right decisions. You have to trust the manufacturers that are typically privately held companies, to do the right thing and monitor them. It is not an easy business to be successful. If you are successful, it is incredibly rewarding if you can actually develop a product for patients who will either die of their disease or to find patients that can live chronically with their disease. I think the whole essence of oncology is we would love to cure you and if we get it early enough, maybe we can but if we cannot, let's at least give you options so that you can live with your disease just like you would live with diabetes for a long time.

CEOCFO: How is business these days?

Mr. Levonyak: Good, we have been in business for five years and every year we have grown. We have a very profitable business. In fact, most unusual to most startup companies, we

actually broke even the first year and year two through five we have shown a profit that has grown significantly every year. I feel as though this will be our best year. Heading into next year, we will probably add another ten maybe fifteen people to grow out of our space here in Dallas Texas and find a new office building. Our goal is to see what it looks like in seven to ten years, hopefully being more of a household name and a go-to company when it comes to either knowledge or patient recruitment.

CEOCFO: Why should the business and investment community pay attention to DAVA Oncology?

Mr. Levonyak: We are the only company in the patient recruitment business that is using this MD-to-MD approach. We are very deep in oncology, so you should pay attention to us if you are interested in the cancer space and if you want depth of knowledge and strategy with the individuals who have practiced medicine over the last twenty years, and a PhD team that is very deep into the science and mechanisms of cancer. We are a company that you can go to that can give you a very creative way to share information and an effective way to enroll patients to clinical trials.

CEOCFO: What should people remember most about the DAVA Oncology story?

Mr. Levonyak: A company that supports oncology drug development and whose results have impacted the advance of cancer research.



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